

**Osteoarthritis Double-Blind Placebo Controlled LifeWave Med
Pain Relief Study**

Report on LifeWave Med pain relief 2-patch system

Protocol number:	IW-MED2012-001
ANSM registration number:	2012-A00838-35
Investigational products: (Class I medical devices in contact with safe skin for less than 12 hours)	1. LifeWave Med pain relief 2-patch system (IceWave) 2. Placebo 2-patch system
Forms:	Non-transdermal patches
Application:	Cutaneous application on both acupuncture points and special points to stimulate nerves
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Sponsor:	LIFEWAVE EUROPE Raheen Industrial Estate ATHENRY, CO. GALWAY IRELAND
Date and report version number:	Final Version 1.0 of June 4, 2013

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PROTOCOL #: IW-MED2012-001

ANSM #: 2012-A00838-35

TITLE OF THE PROTOCOL:

Osteoarthritis Double-Blind Placebo Controlled LifeWave Med Pain Relief Study

SPONSOR SIGNATURES IN ACCORDANCE WITH THE REPORT

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June 4, 2013

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June 4, 2013

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2 SYNOPSIS

ANSM registration #:	2012-A00838-35
Study number:	IW-MED2012-001
Protocol Title:	Osteoarthritis Double-Blind Placebo Controlled LifeWave Med Pain Relief Study
Sponsor:	LIFEWAVE EUROPE
Objectives:	<u>Main Objective:</u> The objective of this study was to evaluate, compared to placebo, patients with nociceptive pain experienced the reduction in pain within minutes of application of active LifeWave Med pain relief 2-patch system patches.
Design:	This was a multicentric, double-blind, placebo controlled study, in two parallel groups: <ul style="list-style-type: none"> - LifeWave Med pain relief 2-patch system (IceWave) - Placebo of 2-patch system
Sample Size:	<u>Analyzed sample size:</u> 100 subjects divided in two groups of 50 (one group with the active patches and the other group with placebo patches).
Number of centers:	5 centers
Inclusion criteria:	<ul style="list-style-type: none"> a. Male or females b. 30-70 years of age c. Nociceptive pain d. Absence of cognitive impairment e. Absence of cutaneous pathology f. Absence of hypoesthesia g. Subjects must have a baseline EVA scale score of 50 mm or greater to be included (scale between 0 and 100 mm) h. Subject, psychologically able to understand the study related information and to give a written informed consent. i. Subject having given freely and expressly her informed consent. j. Subject able to comply with protocol requirements, as defined in the protocol. k. Subject affiliated to a health social security system.
Exclusion criteria:	<ul style="list-style-type: none"> a. Women who are pregnant or nursing a child (negative urinary pregnancy test at the inclusion for women able to procreate) b. Allergy or sensitivity to medical adhesives c. Any individual who does not meet the inclusion criteria d. Subject who had been deprived of their freedom by administrative or legal decision or who is under guardianship. e. Subject in an emergency situation.
Investigational product :	LifeWave Med pain relief 2-patch system (IceWave)
Name / code:	
Galenic form:	Non- transdermal 2-patch system (Class I medical device)
Placebo	Placebo of 2-patch system
Name / code:	
Galenic form:	Non- transdermal 2-patch system (Class I medical device)

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Dosage:	NA
Duration:	One application during one hour
Administration route:	Cutaneous application on acupuncture points (non-transdermal patches)
Safety Parameters:	Analysis of adverse events and adverse reactions.
Efficacy Parameters:	Subjective evaluation of pain with a 0-100 mm Scale EVA
Study Procedures:	Screening visit + Pain evaluation before patches application and 5 minutes, 15 minutes and 1 hour after patches application.
Statistics:	<p><u>Main objective analysis</u></p> <p><u>First line analysis:</u></p> <p>To test whether the difference between both groups (product vs placebo for the 2-patch system) is at least greater than 15 millimeter, a one-tailed t-test (against value 15) for unpaired data was applied on each change from baseline $(t_i - t_0)_{with\ i= t1h}$.</p> <p><u>Second line analysis:</u></p> <p>To test whether the difference between both groups (product vs placebo for the 2-patch system) is at least greater than 15 millimeter, a one-tailed t-test (against value 15) for unpaired data was applied on each change from baseline $(t_i - t_0)_{with\ i= 5, 15\ min}$</p> <p>Comparison between both groups (product vs placebo for the 2-patch system).</p> <ul style="list-style-type: none"> • For each comparison on measurement of pain reduction using scale EVA, an ANOVA model for repeated measures was fitted to the raw data. • A chi-squared test was used to compare at t5min, t15min and t1 hour, on the proportion of volunteers with a decrease of pain (evaluated with scale EVA) from baseline (t0).
Study Duration:	Beginning of study: December 2012 End of study: April 2013 Global duration of the study: 6 months Study duration by subject: approximately 2 hours

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Results- Conclusion	<p>5 minutes after patch application, IceWave patches induced a slight pain reduction, but which was equivalent to the one observed with placebo patches (about 10 mm decrease on the 0-100 mm EVA scale). 15 minutes and one hour after patch application, the pain continued to decrease with the active patches, whereas it stayed stable with the placebo patches. From 15 minutes of application, the difference between active and placebo patches was statistically significant. One hour after application, the difference of pain improvement between both products was the highest (41% of difference between both products, so about 28 mm on the EVA scale). Indeed, the active patches induced a 65% pain decrease (about 41 mm on the 0-100 mm EVA scale) <i>versus</i> only 23% of pain decrease with the placebo patches (about 13 mm on the 0-100 mm EVA scale). The primary end point has then been reached (difference of pain reduction of at least 15mm between active and placebo patches at t1hour) and the effect of active patches <i>versus</i> the placebo ones can be considered as clinically relevant. One hour after patch application, 94% of the subjects felt a pain improvement with the active patches, <i>versus</i> only 48% of the subjects with the placebo patches.</p> <p>Moreover, the patches were very well tolerated as no adverse reaction was observed during one hour of contact with the skin.</p> <p>The IceWave patches are non-transdermal patches that do not put any chemicals or drugs into the body. These patches are a new method of improving pain control by stimulating specific points on the body with a combination of pressure and infrared energy. This approach of pain control would allow avoiding the long term toxic effects of currently available pain medications. The safety and efficacy results obtained in this study show that IceWave patches could be a very interesting approach to pain control, without any secondary effects, allowing immediate and durable pain improvement.</p>
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4 LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

AE	Adverse Event
ANSM	Agence Nationale de Sécurité du Médicament et des produits de santé
CA	Competent Authority
C.N.I.L	Commission Nationale de l'Informatique et des Libertés
CRF	Case Report Form
CRA	Contract Research Associate
C.R.O	Contract Research Organization
C.S.P	Code de la Santé Publique
EC	Ethics Committee
EVA	Echelle Visuelle Analogique (Visual Analogical Scale)
FVFS	First Visit First Subject
GCP	Good Clinical Practice
I.C.H	International Conference on Harmonisation
ICF	Informed Consent Form
LVLS	Last Visit Last Subject
MD	Medical Device
MV	Missing Value
NA	Not Applicable
PAS	Systolic Arterial Pressure
PAD	Diastolic Arterial Pressure
SAE	Serious Adverse Event
SD	Standard Deviation
SEM	Standard Error on the Mean

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5 ETHICS

5.1 Independent Ethics Committee and Competent Authority

The protocol was reviewed and approved by an Independent Ethics Committee (Comité de Protection des Personnes [CPP]) of “Centre Léon Bérard – Sud Est IV- Lyon - France”, on September 4, 2012 and was authorized by the french competent authority (ANSM) on July 27, 2012.

All modifications of the protocol asked by these authorities have obtained the agreement of the principal investigator and the sponsor before being submitted again for approbation.

5.2 Ethical conduct of the study

Declaration of HELSINKI⁽¹⁾

The current revision of the Declaration of Helsinki is the accepted basis for clinical study ethics, and must be fully followed and respected by all engaged in research on human beings. Any exceptions must be justified and stated in the protocol. Independent insurance that subjects are protected can only be provided by an ethics committee and freely obtained informed consent.

Good Clinical Practice⁽²⁾

Good clinical practice is a standard for clinical studies, which encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies. It ensures the studies are ethically justified and scientifically sound, and that the clinical properties of the diagnostic/therapeutic/prophylactic product under investigation are properly documented.

Ethics Committee and Competent Authority⁽³⁾

It is the responsibility of the sponsor or its legal representative to submit a copy of the protocol and detailed patient information sheet and consent form to an ethics committee/institutional review board in order to obtain independent approval to conduct the study. Ethics committee/institutional review board approval must be obtained before the study is started. The approval of the ethics committee/institutional review board must be sent in writing, to the sponsor or its legal representative. The Ethics Committee approval letter must mention the Ethics Committee members and their function.

In parallel or after the Ethics Committee submission, the sponsor or its legal representative must address an authorization request to the French authorities.

Any clinical trial cannot be performed without having obtained the agreement of the Ethics Committee and the inherent authorization of the French authority in a regulatory delay of 60 days beginning at the reception of the file by the French authority.

« Informatique et libertés » Law⁽⁴⁾

The medical data collected close to the patients during the study, are saved in informatics files which are analysed for or by the sponsor in order to evaluate the benefit of the treatment.

These confidential data (each subject is assigned with an anonymous identification code) may be transmitted, if requested, to health authorities.

In accordance with the French law « informatique et libertés », the patient may have an access to his/her data and has the right to correct them close to the CRO, at any moment.

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5.3 Subject information and consent form

It was the responsibility of the investigator(s) to obtain informed consent from each subject participating in the study, after explanation of the aims, methods, benefits and potential hazards of the study.

It was completely and unambiguously clear to each subject that she/he was free to refuse to participate in the study, or that she/he could withdraw her/his consent at any time and for any reason, without incurring any penalty or withholding of treatment on the part of the investigator.

The consent obtaining was done under such conditions that permit to the subject to consider in the best way the ratio benefits/ risks associated to his/her participation in the study.

The investigator insured that the content of the information and consent form was appropriate to the study and that the process for obtaining the consent was in conformity with the applicable regulation.

In the frame of this study, the consent has been obtained before any study-specific procedures were performed, and thus in accordance with the Helsinki declaration.

No subject could be included and/or randomized before having signed the consent form, written in an understandable language.

Each subject received oral and written information concerning the studied product(s), its nature, the duration and the conditions of the study. The consent was personally signed and dated by the subject in two exemplars and by the person in charge of the consent obtaining.

Each subject received an original of the information sheet and consent form, dated and signed. The second original of the signed and dated consent form was archived in the investigator file.

6 INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

The study was planned to be conducted in the following centers:

Center 1 :

CMPR Iris
271 rue des Sources - BP 22
69280 Marcy-l'Etoile/
25, rue André Lwoff
69800 Saint Priest/
63 bis rue Maryse Bastié
69008 Lyon

Center 2 :

CMPR du Bourget
7 rue Rigaud
93 350 Le Bourget

Center 3 :

CSSR Choisy
9 bis rue Ledru Rollin
94 600 Choisy-le-Roi

Center 4 :

CMPR Rosemond
61-67 avenue des Goumiers
13 008 Marseille

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Center 5 :
CMPR Le Floride,
Avenue Thalassa
66421 Le Barcares

The list of the main participants in the study is presented in [Appendix 16.1.4.](#)

7 INTRODUCTION

7.1 Scientific background and rationale of the study

Pain, as defined by the International Association for the Study of Pain, is “an unpleasant sensory and emotional experience usually associated with actual or potential tissue damage, or described in terms of such damage”. In 2001, the Joint Commission on Accreditation of Healthcare Organization (JCAHO) recommended pain as the fifth vital sign (in addition to patient’s temperature, blood pressure, heart rate, and respiratory rate). In the medical, as well as Physical Medicine and Rehabilitation (PM&R) settings, pain is one of the most common reasons for patients seeking care. In North America, the estimated costs of chronic pain, including direct medical expenses, lost income, lost productivity, compensation payments, and legal charges, are approximately \$90 billion a year [Tan, 2005].

It is clear from this brief description that pain is a significant problem worthy of study and that safe and effective treatment of pain can be beneficial for both the patient and society. Chronic musculoskeletal pain could consist of categories such as chronic low back pain, non-inflammatory arthritis (e.g., osteoarthritis), inflammatory arthritis (e.g., rheumatoid arthritis), fibromyalgia and myofascial pain syndrome. Chronic pain treatments include TENS, acupuncture, thermal therapies, lasers, and drugs such as antidepressants, NSAIDs, opioids, and other medications [Tan, 2005]. Therapies involving infrared heat, non-thermal infrared treatments with low energy lasers, acupuncture and electronic modalities, such as microcurrent devices, are all accepted treatments for musculoskeletal pain. Most people who have pain will typically choose either nonprescription analgesics or use prescribed medications for pain control. However, the long term use of nonprescription analgesic medications and prescribed anti-inflammatory drugs and narcotics will cause serious side effects in a significant number of people. The issue of long term toxic effects to all currently available pain medications makes investigation of nontoxic approaches a valuable pursuit. For medical personnel, the relief of pain is both a moral and professional responsibility. It has been shown in multiple double-blind-placebo-controlled clinical studies that LifeWave pain patches reduce pain and provide a thermoregulating effect to the body, promoting the parasympathetic nervous system activity.

The parasympathetic nervous system is one of the main divisions of the autonomic nervous system (ANS). The ANS, in turn, is the component of the nervous system that is responsible for balancing and regulating all of the internal organs and glands, which occurs unconsciously. The parasympathetic system specifically is responsible for controlling the processes of the body that occur when the body is at rest. Activating the parasympathetic nervous system has a cooling and relaxing effect which, in turn elicits the desirable physiological response helping with different physiological functions [Nazeran et al, 2005; Clark, 2005; Budzynski et al, 2008; Nazeran, 2007].

Previous studies have already shown a positive effect of IceWave patches on pain reduction using VAS. One study was conducted on 30 subjects with pain of different origins. Results of this study showed that a significant pain improvement was observed within minutes of patch application. However, this study was not placebo controlled. Another double-blind placebo-controlled clinical study on 60 subjects with knee pain was conducted with application of IceWave patches during 2 days. This study demonstrated that both active and placebo patches induced a pain improvement with an effect significantly more important with the active on the second day. However, no double-blind placebo controlled study evaluated the immediate effect of IceWave patches (in the first hour).

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7.2 Identification and description of the experimental product(s)

The LifeWave Med pain relief 2-patch system patches are non-transdermal patches that do not put any chemicals or drugs into the body. These patches are a new method of improving pain control by stimulating either points on the skin or acupuncture points by reflecting specific wavelengths of visible and infrared light. In short, this is a new method of phototherapy.

Acupressure Mechanism

A textbook definition of acupuncture is the "stimulation of points and channels". The stimulation can be produced by various modalities including needling and or pressure (acupressure) (O'Connor, 1981). Evidence obtained from clinical trials in both acupuncture studies with needles and acupressure studies has determined that point location is important. For example, in studies of nausea using either needle acupuncture or acupressure of the acupoint known as Pericardium 6 (P6) have shown that stimulation of a nearby area has little effect on nausea and is primarily a placebo. Real P6 acupuncture or acupressure shows a consistent 60-70% response rate, whereas sham acupuncture or sham acupressure on a nearby area only a 25-30% response rate, consistent with it being primarily a placebo (Dundee et al., 1992; Bayreuther et al., 1994).

LifeWave Med pain relief 2-patch system patches are a safe and effective, new technology capable of gently stimulating acupuncture points without the use of needles. LifeWave Med's pain relief 2-patch system patches utilize this innovative technology to stimulate acupuncture points on the body for improving the flow of energy in the acupuncture meridians. The patches are designed to stimulate acupuncture points by several mechanisms that involve both acupressure and energetic principles. The self-adhesive patches utilize the principles of Oriental medicine and needleless acupuncture to gently stimulate points on the body that have been used to balance and improve the flow of energy in the human body for thousands of years. Because the patches are non transdermal, the use of these patches results in a natural way of improving the quality of life without any chemicals, drugs or stimulants or sedatives entering the body.

Energetic Mechanism

LifeWave Med pain relief 2-patch system patches reflect energy back into the body and do not have internal power sources that generate energy. The non-toxic materials in the patches act like frequency specific reflectors (narrow-band) as compared to the ceramic fibers found in infrared products, which are broadband reflectors. Placing a LifeWave patch on the skin will allow the patch to trap and passively absorb wide-band infrared energy and re-emit narrow-band infrared energy back into the body. By way of example, infrared wraps contain inorganic ceramic fibers. These inorganic fibers absorb infrared energy from the body and then re-emit the energy across a wide energy band. LifeWave patches contain materials, which mirror back the energy that the body is already emitting. The difference between the LifeWave Med pain relief 2-patch system patches and infrared products is that the LifeWave patches only mirror back a very narrow band of frequencies depending on the patch product selected. In summary, LifeWave patches are designed to deliver infrared wavelengths to enhance the electrical conductivity of the skin and are a new method of stimulating acupuncture points.

Phototherapy

Phototherapy is a scientifically proven light therapy that has been used for decades for benefits such as pain relief and reducing wrinkles. It refers to the stimulation of points on the skin through the use of light. The company has designed an entirely new patch technology around this method that is inexpensive and convenient to use. Our patches are composed of non-toxic organic crystals that are activated by body heat to reflect specific wavelengths of light that affect points on the body when applied to the skin.

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8 STUDY OBJECTIVES

8.1 Primary objective

The objective of this study was to show that when compared to placebo, patients with nociceptive pain experienced a reduction in pain within minutes of application of active LifeWave Med pain relief 2-patch system patches.

8.2 Secondary objective(s)

Not applicable.

9 CONCEPTION OF THE STUDY

9.1 Methodology of the study

The study was:

- ◆ double-blind,
- ◆ randomized,
- ◆ in parallel groups,
- ◆ versus placebo
- ◆ multicentric,
- ◆ on patients with nociceptive pain.

9.2 Study flow chart

Figure 1 - Study flow chart

Procedure	Screening/ Baseline	5 min. post- application	15 min. post- application	1 hour post application
Informed Consent	X			
Medical examination, medical history, previous or concomitant medications	X			
Urinary pregnancy test	X			
Inclusion/Exclusion	X			
Randomization	X			
Subjective Pain Assessment	X	X	X	X
Safety Assessment				X
Exit from Study				X

9.3 Description of the study schedule

- Patients presenting with nociceptive pain established qualification for inclusion and for establishment of the baseline pain measurement. The information was evaluated by the clinical investigators to determine the relevance and appropriateness of the participant. The study investigator obtained consent prior to participation and qualified the patient for participation based

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on the patient meeting requirements of inclusion and exclusion criteria. A clinical examination was made and medical history and concomitant treatments were collected in the CRF. Qualified patients must have had pain level of at least 50 mm on a 0-100mm **Scale EVA**. For women able to procreate, urinary pregnancy test (payable by the Sponsor) must have been negative.

- Once subjects were screened, enrolled, and assigned to a treatment group in a random way. They were patched with LifeWave Med pain relief 2-patch system patches or corresponding placebo patches by the Investigator. All subjects were patched by the same trained person whatever the investigation site.
- Subjects were asked to remain close-by for the evaluations. The investigator worked with the subject to determine which locations were most effective. Once the final location was located and the patches were applied, as directed by the investigator, a stop watch recorded how long it took for the subject begin to experience pain relief. The final patch location was noted on the case report form, as well as how long it took, if prior to the first post-patch evaluation.
- Assessments of pain on Scale EVA were completed at 5 minutes, 15 minutes and 1 hour **starting after application of the patches in their final location**.

9.3.1 Inclusion criteria

- Male or females
- 30-70 years of age
- Nociceptive pain
- Absence of cognitive impairment
- Absence of cutaneous pathology
- Absence of hypoesthesia
- Subjects must have a baseline EVA scale score of 50 mm or greater to be included (scale from 0 to 100 mm)
- Subject, psychologically able to understand the study related information and to give a written informed consent.
- Subject having given freely and expressly her informed consent.
- Subject able to comply with protocol requirements, as defined in the protocol.
- Subject affiliated to a health social security system.

9.3.2 Exclusion criteria

- Women who are pregnant or nursing a child (negative urinary pregnancy test at the inclusion for women able to procreate).
- Allergy or sensitivity to medical adhesives
- Any individual who does not meet the inclusion criteria
- Subject who had been deprived of their freedom by administrative or legal decision or who is under guardianship.
- Subject in an emergency situation.

9.3.3 Withdrawal criteria

Any deviation to the protocol that can affect:

- the primary evaluation criterion,
- the adherence of the subjects to the study schedule,
- the adherence relative to the products use,
- the inclusion / exclusion criteria,

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can be considered as an exclusion criterion. Before any exclusion of the subject from the study, each case will be discussed with the sponsor who will make the final decision if the subject must be excluded from the study.

9.3.4 Premature study exit

9.3.4.1 *Criteria and modalities of premature end of treatment or subject exclusion from the study*

Subjects were free to withdraw from the study at any time if they wish so and for any reason, without having to provide any justification to the investigator.

The investigator had the right to withdraw a subject for any reason, for subject's best interests, including illness or adverse events.

The sponsor may decide to withdraw subjects for major deviation to the protocol, for administrative reasons or for any other valuable reason ethically justified.

Subjects may discontinue the study for the following reasons:

1. *Subject consent withdrawal:* subjects had the right to exit from the study at any time and for any motive, without their right to treatment being affected.
2. *Medical reasons or adverse events:* the investigator had the right to withdraw a subject in case of intercurrent illness or adverse events or if in the investigator's opinion, continuation in the study would be detrimental to the subject's well-being.
3. *Appearance of an exclusion criterion.*
4. *Failure to follow-up:* if a subject did not come to the scheduled visits, several attempts had to be done to try to contact him/her; to obtain the reasons for non-attendance.
5. *Violations and deviations from the protocol.*
6. *Administrative reasons.*

9.3.4.2 *Modalities and calendar of recording data*

Withdrawal due to intercurrent disease or adverse event must be fully documented in the case report form and should include any available and/or appropriate complementary information.

In all cases, the reason for withdrawal was recorded in the case report form. The subject was followed up to state the reason for withdrawal and to establish whether the reason was an adverse event. Since the moment the investigator knew the early termination or exclusion, the withdrawal of the subject was formalized by a visit. If possible, all examinations scheduled for the final study day were to be performed on all subjects who received the investigational product but do not complete the study according to protocol.

The investigator should make every effort to contact subjects who dropped-out of the study early. In the case where no visit was possible, this withdrawal should be recorded by the investigator in the case report form and the source data documentation, and, if necessary, the registered letter with acknowledgement of receipt, to the subject. All the documentation concerning that subject should be as complete as possible.

9.3.4.3 *Modalities for the follow-up of these subjects*

When the premature exit was due to an adverse event, the subject must be followed until the resolution or the stabilization of the symptoms.

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9.4 Treatment(s) administered

9.4.1 Authorized medication(s) and treatment(s)

Any concomitant medication at inclusion of the subject into the study must be reported in the study CRF at the initial visit and was taken into consideration by the Investigator deeming study eligibility.

Any modification on these medications during the study *must* be reported in the study CRF.

Use of any concomitant medication during the study was recorded in the CRF with the following information:

- Indication for use of the treatment;
- Name of the drug, type of formulation, and unit strength;
- Dose administered;
- Duration of treatment (start and stop date).

9.4.2 Prohibited Treatment(s) and Medication(s)

No analgesic medication was authorized during the study duration.

More generally, subjects were not allowed, during the study, to take any medication which might interfere with the performance or interpretation of the study end point evaluations specified in this protocol, unless the subject elects to withdraw from the study.

The data from subjects who repeatedly violate these medication restrictions were excluded from efficacy analysis.

9.4.3 Product(s) used but not studied

Not applicable.

9.5 Investigational products

9.5.1 Description of the investigational product(s)

9.5.1.1 *LifeWave Med pain relief 2-patch system (IceWave)*

Figure 1. Picture of LifeWave Med pain relief 2-patch system



Set of LifeWave Med pain relief 2-patch system consists of one white (positive polarity) and one dark (negative polarity).

LifeWave Med pain relief 2-patch system consists in two non-transdermal patches: one white (positive polarity) and one dark (negative polarity) (IceWave patches).

The LifeWave Med pain relief 2-patch system patches are disposable nontransdermal patches. The LifeWave patches contain a polyester pad, which is sealed within a polyethylene shell. The top side of

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the patch is composed of water- resistant polyethylene film made by the 3M Corporation (Part No. A19-48G) that is sealed to the bottom portion that is composed of water-resistant single coated Medical-grade polyethylene tape also made by the 3M Corporation (Part No. 1525L). The bottom side of the Medical-grade polyethylene tape that attaches the IceWave patches to the body is coated with a hypoallergenic pressure sensitive Acrylate adhesive that allows the patch to adhere to the body. Because of the nature of construction none of the materials in the IceWave patches enter into the body making the LifeWave IceWave patches non-transdermal patches.

9.5.1.2 Placebo of 2-patch system

Both the white and dark placebo patches are constructed as follows : The top side of the patch is composed of water-resistant polyethylene film made by the 3M Corporation (Part No. A19-48G) that is sealed to the bottom portion that is composed of water-resistant single coated Medical-grade polyethylene tape also made by the 3M Corporation (Part No. 1525L). The bottom side of the Medical-grade polyethylene tape that attaches the patches to the body is coated with a hypoallergenic pressure sensitive Acrylate adhesive that allows the patch to adhere to the body. Placebo patches do not contain the polyester pad or any solution.

9.5.2 Dosage

Each patch system was in contact with the skin during one hour.

9.5.3 Instructions of use

9.5.3.1 Administration route and recommendation(s)

1. The LifeWave patches are removed from the package.
2. The liner is removed from the adhesive backing
3. The LifeWave patches are applied to the skin, using the medical grade adhesive side of the patch to secure patch placement. All patches were applied by the same trained person, whatever the investigation site.

SCRIPT FOR PATCHING SUBJECTS AND DETERMINING BEST AND FINAL LOCATION:

Tell the subject: *“This is an ‘electrical method’ of pain control so it can work very quickly in reducing pain if the patches are placed in a helpful location. I am going to move the patches around to different locations and I want you to tell me each time I move the patches if the pain has changed and by how much compared to before the patches were placed there.”*

INVESTIGATOR: The ideal scenario is to remove the pain completely. If at any placement, the pain has completely subsided, remove the masking tape, remove the paper from the patches and affix to body. Record the EVA scale score.

You only have to wait 20 seconds to ask if the pain has changed, if the pain has not changed move to the next position.

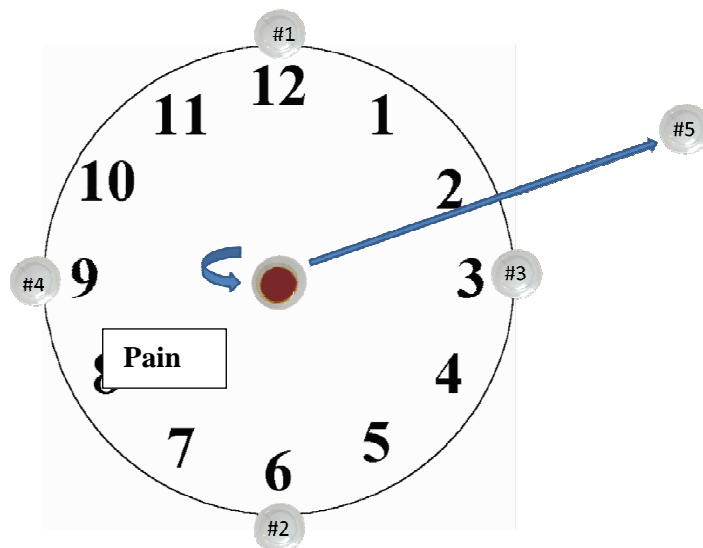
The clock method

First, have the person point with one finger to the location where the pain is most intense. This will be considered the center of a clock and the dark patch will be placed on this location using a strip of medical tape to temporarily keep the dark patch in position.

1. For position #1 put the white patch, using a strip of medical tape, 2,5 to 5 cm above the dark patch at the 12 O'clock position. Ask the subject is there a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the

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- amount of decrease in pain, but continue to next position. If the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions.
- For position #2 leave the dark patch on the pain and only move the white patch using a strip of medical tape to the bottom of the clock at the 6 O'clock position. Ask the subject is there a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the amount of decrease in pain, but continue to next position. If the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions.
 - For position #3 leave the dark patch on the pain and only move the white patch using a strip of medical tape to the right side of the clock at the 3 O'clock position. Ask the subject is there a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the amount of decrease in pain, but continue to next position. If the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions.
 - For position #4 leave the dark patch on the pain and only move the white patch using a strip of medical tape to the left side of the clock at the 9 O'clock position. Ask the subject is there a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the amount of decrease in pain, but continue to next position. If the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions.
 - For position #5 leave the dark patch on the pain and draw an imaginary line thru the body to the opposite side of the body and put the white patch there using a strip of medical tape. For instance if it is low back pain the line going thru the body would end up on the lower abdomen. If it is shoulder pain and the dark patch is on the back of the shoulder then only move the white patch to the front side of the shoulder. Ask the subject is there a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the amount of decrease in pain, but continue to next position. If the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions.

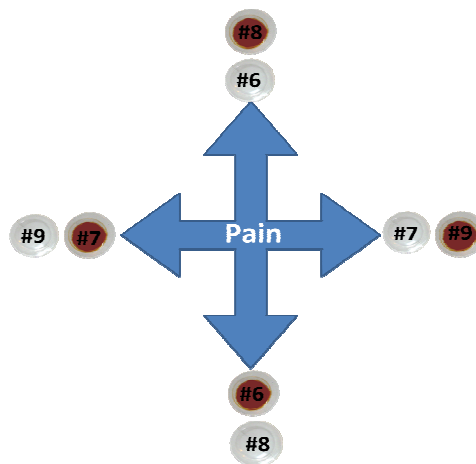


The bracketing method

- For position #6 again have the person point with one finger to the location where the pain is most intense. Now you will try to "bracket" the pain, which for position #6 means you will put the patches above and below the pain. Place the white patch using a strip of medical tape 2.5 to 5 cm above the area of pain and the dark patch 2.5 to 5 cm below the area of pain. Ask the subject is there a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the amount of decrease in pain, but continue to next position. If

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- the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions.
7. For position #7 again you will try to "bracket " the pain, which for position #7 means you will place the white patch using a strip of medical tape 2.5 to 5 cm to the right of the area of pain and the dark patch 2.5 to 5 cm to the left of the area of pain. Ask the subject is there a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the amount of decrease in pain, but continue to next position. If the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions.
 8. For position #8 again you will try to "bracket " the pain, which for position #8 means you will place the white patch using a strip of medical tape 2.5 to 5 cm below the area of pain and the dark patch 2.5 to 5 cm above the area of pain. Ask the subject is there a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the amount of decrease in pain, but continue to next position. If the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions.
 9. For position #9 again you will try to "bracket " the pain, which for position #9 means you will place the white patch using a strip of medical tape 2.5 to 5 cm to the left of the area of pain and the dark patch 2.5 to 5 cm to the right of the area of pain. Ask the subject is there a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the amount of decrease in pain, but continue to next position.. If the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions. If the pain is not significantly reduced by at least 80% from baseline move to position #10.



Whole body method

10. For position #10 place a WHITE patch on the bottom of right foot using a strip of medical tape, and the dark patch on bottom of left foot (on the acupuncture position named Kidney 1). Ask the subject is there a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the amount of decrease in pain, but continue to next position. If the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions. If pain has not been reduced in 20 seconds, go back to the location that felt like it had the most effect and affix there. Remove all adhesive and stick firmly to skin.
11. Position #11 (may not be applicable): If at any time the pain gets worse, switch the location of the patches. Move the white patch using a strip of medical tape to the location where the dark patch was placed and move the dark patch to the location where the white patch had been placed.

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Then ask the subject is there any change in a decrease in pain? Investigator: Is the decrease at least 80% from baseline? If not, continue to next position. If yes, then note the amount of decrease in pain, but continue to next position. If the pain is completely resolved take the backing off of the patches and apply the patches to the skin in the identified positions.

If pain has not been reduced by at least 80% by any of the patch placements, then use the location that had the best effect as the final position. If there was no change at any patch placement use, Kidney 1 (soles of feet) as final position.

9.5.3.2 Labelling

Study articles were coded to distinguish between active and placebo, but the code was kept blind for the investigators until the code break is requested.

Example of labelling

The labelling of the products was realized by the Sponsor.

- Coordinating Investigator name: Dr. Pierre Volckmann
- Emergency phone number :
- Study number : IW-MED2012-001
- Product code :
- Batch number :
- Storage conditions :Store in a cool dark place away from x-ray machines and other diagnostic equipment.
- Expiration date : To use before.....
- Legal mention :For clinical trail only. To use under strict medical supervision. Keep out of reach of children

9.5.3.3 Storage conditions

Study articles were kept away from prolonged exposure to sunlight and extreme temperatures, kept out of reach of children and stored in a cool dark place away from x-ray machines and other diagnostic equipment.

9.5.3.4 Dispensing and accountability of investigational product(s)

The tested products were only be dispensed under the supervision of a physician approved for the study. The investigator was responsible for dispensing the study products to the subjects who were included in the study.

9.5.4 Treatments allocation – Randomisation - Blinding

Each product was allocated in a random way to each subject. The randomization list is presented in [Appendix 16.1.9](#).

9.5.5 Follow-up of adherence to treatments use

The subject's participation in the study did not exceed 2 hours, so subject compliance was not expected to be an issue. Subjects were asked to remain on-site until after the one hour evaluation.

9.6 Evaluation variables

9.6.1 Evaluation criteria

9.6.1.1 Main evaluation criterion

Primary endpoint was measured by a minimum of 15 millimeter reduction on the EVA pain scale in the post-baseline pain assessments in the active patch groups when compared to the placebo treatment groups, after one hour of patches application.

9.6.1.2 Secondary evaluation criteria

Secondary endpoint was measured by

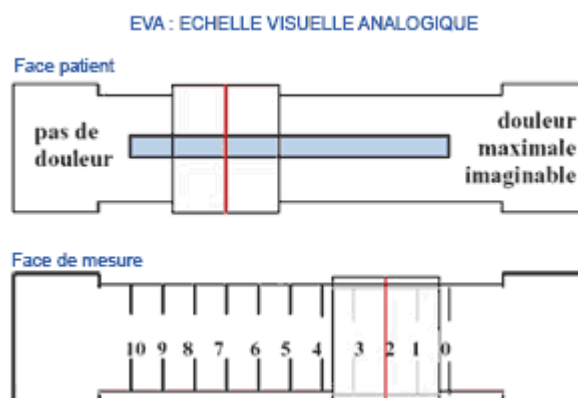
- a minimum of 15 millimeter reduction on the EVA pain scale in the post-baseline pain assessments in the active patch groups when compared to the placebo treatment groups, after 5 and 15 minutes of patches application
- a reduction in pain levels for the duration of the one-hour period.

9.6.2 Efficacy Evaluation

9.6.2.1 Description of the efficacy parameters

The **Scale EVA** is a commonly used pain scale in France. It consists of a 100mm horizontal line with verbal anchors indicating a continuum from “no pain” at one end to “severe pain” (“pain as bad as it could be”) at the other end. The patient is asked to mark on the line the pain he or she is now experiencing (e.g., how bad is your pain?).

The **Scale EVA** is simple to use, sensitive to changes in pain intensity; also with good sensitivity to treatment effects. The **Scale EVA** gives reproducible results and it has positive association with other self-report measures. Also, it can be used to reassess pain in the same patient at different times.



9.6.2.2 Method and calendar for measure, collect and analyze the efficacy parameters

Pain evaluation with Scale EVA occurred at baseline, before patches application. The Scale EVA was repeated at 5 minutes, 15 minutes and 1 hour after either the placebo or active LifeWave Med pain relief 2-patch system patches were applied.

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9.6.3 Safety Evaluation

The subject's exposure to the study article was limited to less than two hours. A safety check, i.e., a review of whether or not one of the anticipated adverse events listed in the risk assessment has occurred, was recorded at the completion of the subject's participation. An adverse event form was completed for any reported reactions. For serious adverse events, the Principal Investigator followed-up with the subject within a week to obtain another statement and discover if symptoms worsened, reduced, or subsided. This was reported to the Sponsor within 48 if the event has become serious. Otherwise, regular reporting procedures were followed.

Safety assessment occurred after the patches have been removed, at the completion of the subject's participation.

9.6.4 Measures to be taken to guarantee safety in case of failure of the MD included isolated dysfunction without clinical consequence as well as bad use

Non applicable

9.6.5 Adverse Reactions

Expected adverse reactions are listed below.

Redness and swelling – The only known risks to wearing the LifeWave patches are allergic skin reactions in people who are allergic to adhesives found on medical tapes. The only contact between the patch device and the body is an adhesive layer; this is made by 3M and is hypoallergenic; 1 in 10,000 people are allergic to this adhesive

Itching – some itching may occur, but this is relatively rare.

Inflammation – no inflammation has occurred with the patch as long as it is not worn more than 24 hours at a time, and as long as the patch is placed on a different place each day.

The potential health risks from participation in this study were very minimal and are essentially limited to allergic skin rashes caused by the FDA approved medical adhesive, which is made by the 3M Company. If the adhesive used in the patches does cause significant irritation to skin at the location of application, the patches were removed and the skin area washed with soap and water and the participant discontinued their participation in the study.

9.7 Data Quality Assurance

9.7.1 Source data identification

All clinical data in the protocol and collected by the investigator were notified in the subjects Case Report Form.

9.7.2 Collection and data control

The case report forms were designed to identify each subject by a subject number and, where appropriate, subject's initials. One Case Report Form existed for each subject participating in the study. The case report form was completed legibly, using a black ballpoint pen. Erroneous values and/or text were not erased. Instead, the error was crossed out with a single line, the correct value/text added, and the correction signed, initialled and dated by the investigator(s).

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9.7.3 Access right to source data

In accordance with good clinical practices and the standards of the data protection law, data obtained in the course of a biomedical research has to be treated confidentially to guarantee the subjects' privacy.

The investigator agreed that, subject to local regulations and ethical considerations, the sponsor representatives designee and/or any regulatory agency may have direct access to all study records, CRFs, corresponding subject medical records, study drug dispensing records and study drug storage area, and any other documents considered source documentation. The investigator also agreed to assist the representative, if required.

9.8 Data management

9.8.1 Data entry and treatment

Case report forms data were entered in specific data bases MS Excel.

Then a quality control of 10% of the CRF was realized by the Project Manager. The project manager or either person mandated by him ensures the coherency between captured data on computer and written data in the CRF.

When all case report forms were captured and that all check-out of data was done the database was put on read-access.

9.8.2 Data storage

Informatics' data sheets as well as their updates were saved according to Dermscan SOP and stayed at the disposal of anyone requiring a see them.

9.8.3 Blind breaking

Unblinding of the assigned treatments occurred after the completion of the following steps:

1. All CRF data were entered into the computer;
2. All data clarifications, if any, were resolved;
3. Major deviations or intercurrent events, if any, were defined and identified;
4. All information necessary to analyze the data was integrated into the data base;
5. The database was formally locked.

9.9 Statistics

The statistical analysis was performed by the biostatistician of Dermscan.

9.9.1 Description of the statistical methods envisaged, and if applicable, of the interim analysis' calendar

Data description:

Data of pain measured with a scale EVA was summarized in tabular form with descriptive statistics (mean, median, standard deviation, standard error of the mean, minimum and maximum values, number of valid values and number of missing values) computed at each time points (t0 (baseline), t5min, t15min and t1 hour) and for the absolute changes ($\Delta_i = t_i - t_0$) and the relative changes ($(\Delta_{i\%} = (t_i - t_0)/t_0 * 100$) from baseline (t0) with i=5min, 15min, and 1h, for each studied group (3 and 4).

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Data of proportion of volunteer with a decrease from baseline (t0) of pain were summarized in tabular form with counts and percentage at t5min, t15min and t1 hour.

First line analysis:

To test whether the difference between both groups at least greater than 15 millimeter, a one-tailed t-test (against value 15) was applied on each change from baseline (ti-t0) with i= t1h.

Second line analysis:

- To test whether the difference between both groups was at least greater than 15 millimeter, a one-tailed t-test (against value 15) was applied on each change from baseline (ti-t0) with i=5min,15min
- On the absolute change (ti-t0):

For the comparison between groups on measurement of pain reduction using scale EVA, an ANOVA model for repeated measures was fitted to the raw data with:

- within subject effect : time with 4 levels
- between subject effect : product with 2 levels

Specific contrasts of interest were constructed to assess:

- the change between each (ti)with i=5min, 15min and 1h from baseline (t0) within each group
 - whether the difference between group 3/group 4 is significant in term of change from baseline (ti-t0)i=5min,15min or 1h.
- A chi-squared test was used to compare: at t5min, t15min and t1 hour, the proportion of volunteer with a decrease of pain (evaluated with scale EVA) from baseline (t0)

For all the analyses, assumptions underlying the model were checked. In case of strong deviation, alternative modelling approach, (e.g. non parametric tests) or appropriate data transformations were investigated.

9.9.2 Determination of sample size

The primary end point of this study was to detect a difference at least 15 mm one hour after patch application between the group “product” and the group “placebo” in term of reduction of pain.

Review of data generated in previous studies using similar scale EVA suggest that 15 mm is a good estimation of the standard deviation for the distribution of the change assessed with scale EVA for each group of treatment (see Khwaja SM, Minnerop M, Singer AJ. Comparison of ibuprofen, cyclobenzaprine or both in patients with acute cervical strain: a randomized controlled trial. CJEM. 2010 Jan;12(1):39-44).

The table below presents the sample size required to detect a difference of 15 mm between product and placebo groups, with a power of 95% using a one t-test at the 5% significance level.

Calculation was performed using the PROC POWER procedure (option *twosamplemeans*) of the statistical software SAS 9.2 for windows. The parameters used were:

- $\Delta=10$ or 15
- SD= 15
- Power : 70 to 95% by 0.05

Computed N Per Group				
Index	Mean2	Nominal Power	Actual Power	N Per Group
1	10	0.70	0.702	22
2	10	0.75	0.751	25
3	10	0.80	0.806	29
4	10	0.85	0.859	34
5	10	0.95	0.952	50
6	15	0.70	0.732	11
7	15	0.75	0.767	12
8	15	0.80	0.824	14
9	15	0.85	0.868	16
10	15	0.95	0.955	23

Moreover, a pilot study carried out in 30 subjects has shown that application of LifeWave pain relief patches (IceWave patches) had a highly significant ($p < 0.001$) effect in attenuating the intensity and perception of severity of pain. The statistical power considering the effect size (% reduction in pain, sample number, and level of significance) from these pilot data was at least 90%. Based upon this pilot study, and the calculation of sample size above, a sample size of 75 subjects per group should be sufficient to show a difference of 15 mm between product and placebo group if this is a real difference.

9.9.3 Statistical significance degree

All statistical tests were assessed at $\alpha = 5\%$ level of significance in a bilateral approach, except for the comparisons with the theoretical value of 15 mm, which were made using a one-tailed t-test.

9.9.4 Procedure for accounting missing, unused, and spurious data

No strategy for taking in charge missing data has been defined. Data that are not valid or missing were considered and treated as missing data.

9.9.5 Changes in the initial statistical analysis plan

The following analysis was added:

On the relative change in $[(t_i - t_0) - t_0 * 100]$:

For the comparison between groups on measurement of pain reduction using scale EVA, an ANOVA model for repeated measures was fitted to the relative change outcome with:

- within subject effect : time with 3 levels
- between subject effect : product with 2 levels

Specific contrasts of interest were constructed to assess:

- the relative change between each $(t_i)_{\text{with } i=5\text{min, } 15\text{min and } 1\text{h}}$ from baseline (t_0) within each group
- whether the difference between groups is significant in term of relative change from baseline $[(t_i - t_0) - t_0 * 100]_{j=5\text{min, } 15\text{min or } 1\text{h}}$.

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9.9.6 Choice and definition of the population to be analyzed

Only the Full Analysis Set (FAS) was considered for the statistical analysis.

FAS (Full Analysis Set): any subject included and randomized in the study with at least a basal value. The whole randomized population was used for safety analysis.

9.10 Administrative Procedures

9.10.1 Protocol changes

During the study, the following change to the protocol was implemented: it was decided to include all types of nociceptive pains and not only pains related to degenerative osteoarthritis as initially planned, because of recruitment issue. Moreover, all types of nociceptive pains are likely to be treated by IceWave patches and degenerative osteoarthritis origin was finally found to be too restrictive.

9.10.2 Protocol deviations

All protocol deviations are listed in this clinical report in paragraph 10.2.

9.10.3 Archiving of study data and documents

The sponsor should archive the protocol, documentation, approvals and all other essential documents related to the study, including certificates that satisfactory audit and inspection procedures have been carried out, for 15 years. DERMSCAN will archive all documents (including ICF and CRFs) concerning the study as detailed below:

- All documents must be archived in a secure place and treated as confidential material.
- All the documents relating to this study will be archived for one year maximum at DermScan before being sent to the society LOCARCHIVES (Parc Industriel de la Plaine de l'Ain, Allée des Cèdres, 01150 SAINT-VULBAS - FRANCE).
- Data will be archived securely as digital and paper version for 15 years from the date of dispatch of the final report's acceptance.

At the end of this period, the study archives will be destroyed only when stipulated in writing by the sponsor.

9.10.4 Audit and inspection

No audit and inspection occurred during the study.

9.10.5 Insurance

The sponsor has subscribed an insurance contract to cover the liability of the investigators, the sponsor himself and anyone involved in the study.

The copy of the insurance certificate is presented separately in the EC and CA submission file.

9.10.6 Publication

The sponsor reserves the right to review all the manuscript(s) and abstract(s) before their submission for publication or presentation. Publication of data will be at the discretion of the sponsor

This is not intended to restrict or hinder publication or presentation, but to allow the sponsor to protect proprietary information and to provide comments based on information that may not yet be available to the investigator(s).

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10 STUDY SUBJECTS

10.1 Disposition of subjects

The table below presents a global synthesis of the recruited population in this study:

Table 1- Number of subjects included and analysed

	Number (n)
Randomised subjects	100 (50 active patches and 50 placebo)
Subjects who ended the study normally	100 (50 active patches and 50 placebo)
Subjects included in the data analysis	100 (50 active patches and 50 placebo)

10.2 Protocol deviations

10.2.1 Number of subjects

The number of subjects included was below the planned sample size (100 subjects instead of 150 subjects) because of recruitment problems. However, according to the sample size calculation presented in paragraph 9.9.2., a sample size of 50 subjects by group (so, a total of 100 subjects) could be considered as enough to show significant differences.

10.2.2 Inclusion criteria

None deviation was observed.

10.2.3 Medical history

As explained in paragraph 9.10.1, the pain origin was not only degenerative osteoarthritis but all nociceptive pains (cf [Appendix 15.2.4.1](#)).

10.2.4 Prohibited treatments

No deviation.

10.2.5 Missing data

No missing data.

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11 EFFICACY EVALUATION

11.1 Data sets analysed

All subjects randomized were analyzed.

Then, the analysis population consisted in 50 subjects for active patches and 50 subjects for placebo patches.

11.2 Demographic and other baseline characteristics

11.2.1 General characteristics of the studied population

The observations concerning all included subjects are presented in [Appendix 16.2.4.1](#). The table below presents a synthesis of these data.

Table 2- General characteristics of the subjects

Product	Number of subject analyzed	Number of subject by center	Gender	Age	Height	Weight
Active patches (RDEYH36-FR)	50	Center 1 : 45 Center 2 : 0 Center 3 : 0 Center 4 : 5 Center 5 : 0	33 F 17 M	59 ± 1 years (between 31 and 70)	1.67 ± 0.01 m (between 1,50 and 1,83 m)	71 ± 2 kg (between 43 and 118kg)
Placebo patches (RDEYH38-FR)	50	Center 1 : 45 Center 2 : 0 Center 3 : 0 Center 4 : 5 Center 5 : 0	40 F 10 M	59 ± 2 years (between 31 and 70)	1.65 ± 0.01 m (between 1,50 and 1,82 m)	72 ± 2 kg (between 46 and 120kg)

Legend : F : female, M : male

The group having received the active patches and the group having received the placebo patches were homogeneous in term of age and physical characteristics (height and weight). A little more men were included for the active patches than for the placebo patches (17 versus 10). Because of recruitment issues, the majority of the subjects were included in Center 1.

11.2.2 Other baseline characteristics

11.2.2.1 Initial clinical examinations

The table below presents the result synthesis of the initial clinical examination (PAS, PAD and pulse rate).

Table 3– Initial clinical examination

Product	PAS	PAD	Pulse rate
Active patches (RDEYH36-FR)	126 ± 2 mm Hg (between 100 and 150)	71 ± 1 mm Hg (between 60 and 80)	71 ± 0.4 bpm/min (between 70 and 80)
Placebo patches (RDEYH38-FR)	126 ± 2 mm Hg (between 100 and 150)	70 ± 1 mm Hg (between 50 and 90)	72 ± 1 bpm/min (between 60 and 90)

All clinical examinations were judged as normal by the investigators.

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11.2.2.2 Pain origin

The origin of the nociceptive pain treated by the patches was classified into three different categories: arthrosis (and associated pathologies), surgery and traumatology. The repartition of these three categories is summarized in the table below. The individual data are presented in [Appendix 16.2.4.1](#).

Table 4- Origin of pain treated by the patches

Product	Arthrosis	Surgery	Traumatology
Active patches	32 subjects (64%)	11 subjects (22%)	7 subjects (14%)
Placebo patches	22 subjects (44%)	24 subjects (48%)	4 subjects (8%)

11.2.2.3 Basal values of efficacy parameters

Before patch application, the average pain value (evaluated on the 0-100 mm EVA scale) was 64 ± 2 mm (between 50 and 100 mm) for the “active patches group” and 59 ± 2 mm (between 50 and 90 mm) for the “placebo patches group”.

11.2.2.4 Other baseline characteristics

The final patch location and the time necessary to obtain pain improvement if inferior to 5 minutes, are described in [Appendix 16.2.4.4](#).

11.2.3 Subject Medical History and previous medications

Tables in [Appendix 16.2.4.2](#) and [16.2.4.3](#) present the medical history and previous medications of all subjects at inclusion.

11.3 EFFICACY EVALUATION

The individual data are presented in [Appendix 16.2.6](#). The details of the statistical analysis are presented in [Appendix 16.1.11](#). A synthesis of the results is presented below.

11.3.1 Descriptive statistics

The table and graphs below show, for both products, the evolution of the average pain (in mm on the EVA scale) over time, as well as the pain reduction in mm and percentage for each product.

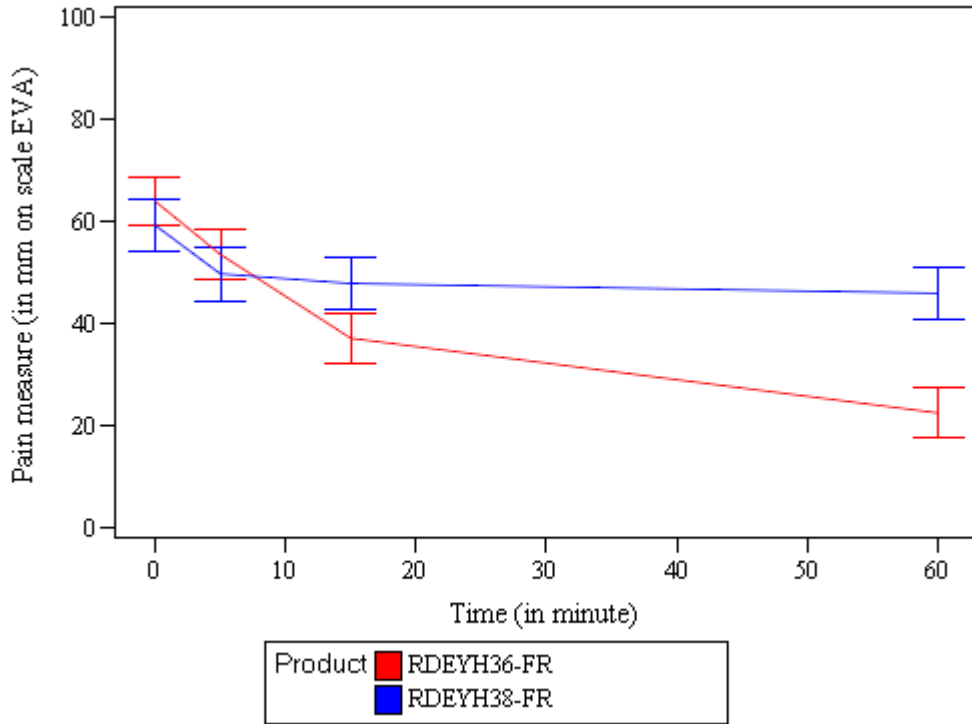
Table 5- Pain values (in mm) over time and decrease of pain vs T0 (in mm and percentage)

Product	Time point	Pain value (in mm) Mean ± SEM	Decrease of pain vs T0 (in mm) Mean ± SEM	Statistical result (Ti vs T0)	Decrease of pain vs T0 (in %) Mean ± SEM
Active patches (RDEYH36-FR)	T0	64.0 ± 2.0	NA	NA	NA
	T5min	53.6 ± 2.6	-10.4 ± 1.7	p<.0001	-17 ± 4%
	T15min	37.2 ± 2.4	-26.8 ± 2.0	p<.0001	-42 ± 4%
	T1h	22.6 ± 2.7	-41.4 ± 2.8	p<.0001	-65 ± 4%
Placebo patches (RDEYH38-FR)	T0	59.3 ± 1.7	NA	NA	NA
	T5min	49.8 ± 2.4	-9.5 ± 1.8	p<.0001	-16 ± 4%
	T15min	47.9 ± 2.8	-11.4 ± 2.2	p<.0001	-20 ± 4%
	T1h	46.0 ± 3.3	-13.3 ± 2.7	p<.0001	-23 ± 4%

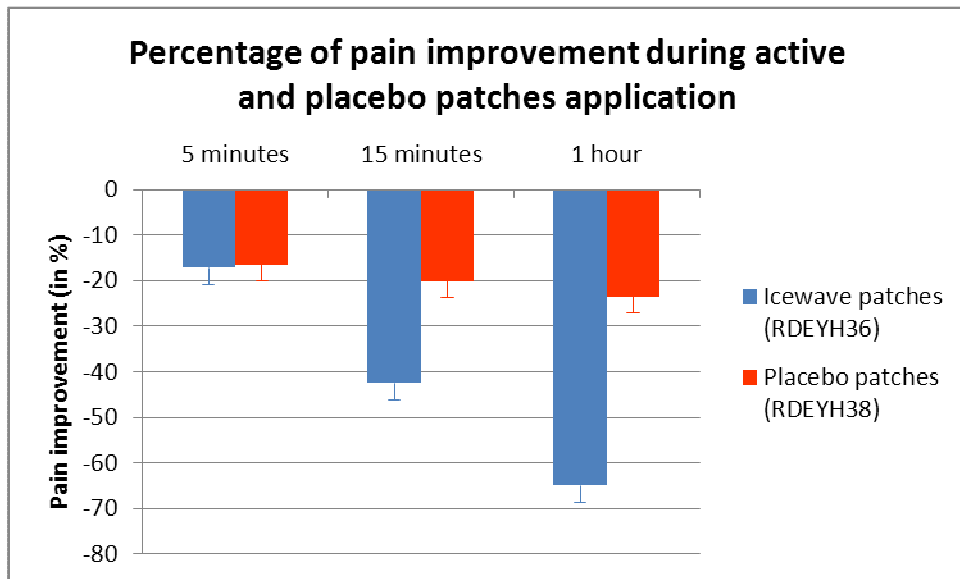
From 5 minutes to one hour after patch application, both products (active and placebo patches) induced a significant pain improvement.

5 minutes after patch application, IceWave and placebo patches induced quite the same pain decrease (-10.4 ± 1.7 mm on the EVA scale for IceWave *versus* -9.5 ± 1.8 mm for placebo). However, 15 minutes and one hour after patch application, the pain reduction improved with active patches, whereas the pain reduction stayed quite stable over time with placebo patches. After one hour of patch application, the difference between active and placebo patches was the biggest: active patches induced a significant 65% pain decrease (-23 ± 3 mm on the EVA scale), whereas placebo patches induced only a 23% pain decrease (-13 ± 3 mm on the EVA scale).

Graph 1- Evolution of pain over time



Graph 2- Percentage of pain improvement



11.3.2 Primary efficacy criterion

The primary efficacy criterion was to evaluate if the pain decrease in the active patch group was superior of minimum 15 millimeter on the EVA pain scale when compared to the placebo patch group, after one hour of patch application.

The statistical results are presented in the table below.

Table 6- Product comparison at t1h

Comparison	Time point	Difference of pain reduction between both products (in mm) Mean ± SEM	Statistical results (comparison between products)	Statistical results (comparison against value 15)	Difference of pain reduction between both products (in %) Mean ± SEM
Active patches (RDEYH36-FR) vs Placebo patches (RDEYH38-FR)	T1h-T0	-28.1 ± 3.9	p<0.0001 [§]	p<0.0006 [°]	- 41 ± 5 %

[§]: contrasts from linear model for repeated measures

[°]: p-value obtained from one-tailed unpaired t-test against value (-15)

After one hour of patch application, the difference of pain reduction between both products was significantly higher than 15 mm (-28.1 ± 3.9 mm, p=0.0006). The active patches induced a pain improvement higher than the placebo patches: this difference was of 41% between both products.

11.3.3 Secondary efficacy criteria

11.3.3.1 Product comparison after 5 and 15 minutes

Table 7- Product comparison at t5 minutes and t15 minutes

Comparison	Time points	Difference of pain reduction between both products (in mm) Mean ± SEM	Statistical results (comparison between products)	Statistical results (comparison against value 15)	Difference of pain reduction between both products (in %) Mean ± SEM
Active patches (RDEYH36-FR) vs Placebo patches (RDEYH38-FR)	T5min-T0	-0.9 ± 3.0	p=0.7676 [§]	p=1.0000 [°]	-1 ± 5 %
	T15min-T0	-15.4 ± 3.0	p<0.0001 [§]	p=0.4468 [°]	-22 ± 5 %

[§]: contrasts from linear model for repeated measures

[°]: p-value obtained from one-tailed unpaired t-test against value (-15)

After 5 minutes of patch application, there was not any significant difference between active and placebo patches (p=0.7676). After 15 minutes of patch application, the difference between active and placebo patches was statistically significant (with a pain improvement higher for active patches). This difference was not different from 15 mm : -15.4 ± 3.0 mm (22 ± 5 % of difference between both products).

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11.3.3.2 Proportion of subjects with a pain decrease

The table below presents the proportion of subjects with a pain decrease at t5min, t15min and t1h after patch application, for each product, with the statistical comparison of both products.

Table 8- Proportion of subjects with a pain decrease

Time points	Active patches (RDEYH36-FR)	Placebo patches (RDEYH38-FR)	Statistical results (comparison between products)
T5min-T0	56%	48%	0.4233*
T15min-T0	92%	50%	<0.0001*
T1h-T0	94%	48%	<0.0001*

*: Chi-square test

After 5 minutes of patch application, the proportion of subjects with a pain improvement was not different between the active and placebo patches (respectively 56% and 48%, p=0.4233).

However, after 15 minutes and 1 hour of patch application, the proportion of subjects with a pain improvement was significantly higher with the active patches than with the placebo patches :

- at t15min : 92% versus 50% (p<0.0001)
- at t1h : 94% versus 48% (p<0.0001)

12 SAFETY EVALUATION

12.1 Extent of Exposure

No subject stopped the patch application following intolerance reactions. All the subjects were in contact the patches during one hour.

12.2 Adverse events

No adverse event or adverse reaction occurred during the study.

12.3 Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

No death was reported. No serious adverse event was reported.

12.4 Clinical laboratory results

Not applicable.

12.5 Vital Signs, Physical Findings, and Other Observations Related to Safety

Not applicable.

12.6 Safety conclusions

The patches were considered as very well tolerated as none adverse reaction was observed during one hour of application.

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13 DISCUSSION AND OVERALL CONCLUSION

The objective of this study was to show that, compared to placebo, patients with nociceptive pain experienced a reduction in pain within minutes of application of active LifeWave Med pain relief 2-patch system patches.

100 subjects were analyzed: 50 received the active patches and 50 subjects received the placebo patches. Assessments of pain on Scale EVA were completed before patch application and then, at 5 minutes, 15 minutes and 1 hour starting after application of the patches in their final location. All the patches were applied in blind by the same trained person.

5 minutes after patch application, IceWave patches induced a slight pain reduction, but which was equivalent to the one observed with placebo patches (about 10 mm decrease on the 0-100 mm EVA scale). 15 minutes and one hour after patch application, the pain continued to decrease with the active patches, whereas it stayed stable with the placebo patches. From 15 minutes of application, the difference between active and placebo patches was statistically significant. One hour after application, the difference of pain improvement between both products was the highest (41% of difference between both products, so about 28 mm on the EVA scale). Indeed, the active patches induced a 65% pain decrease (about 41 mm on the 0-100 mm EVA scale) *versus* only 23% of pain decrease with the placebo patches (about 13 mm on the 0-100 mm EVA scale). The primary end point has then been reached (difference of pain reduction of at least 15mm between active and placebo patches at t1hour) and the effect of active patches *versus* the placebo ones can be considered as clinically relevant. One hour after patch application, 94% of the subjects felt a pain improvement with the active patches, *versus* only 48% of the subjects with the placebo patches.

Moreover, the patches were very well tolerated as no adverse reaction was observed during one hour of contact with the skin.

The IceWave patches are non-transdermal patches that do not put any chemicals or drugs into the body. These patches are a new method of improving pain control by stimulating specific points on the body with a combination of pressure and infrared energy. This approach of pain control would allow avoiding the long term toxic effects of currently available pain medications. The safety and efficacy results obtained in this study show that IceWave patches could be a very interesting approach to pain control, without any secondary effects, allowing immediate and durable pain improvement.

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14 TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

Not applicable.

15 REFERENCES LIST

15.1 Ethical aspect

- 1 - WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI/ Ethical Principles for Medical Research Involving Human Subjects- Helsinki Declaration (1964) and its successive updates
- 2 - ICH TOPIC E6/ Note for guidance on Good Clinical Practice- CPMP / ICH / 135 / 95, January 1997
- 3 - LOI HURIET SERUSCLAT/ CSP Titre II – Recherches Biomédicales- n°88-138 du 20 décembre 1988 modifié par la loi française 2004-806 du 9 août 2004, concernant la santé publique
- 4 - LOI "INFORMATIQUE ET LIBERTES"/ Loi n°78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés mise à jour par la loi n°2004-801 du 6 août 2004 concernant la protection des personnes pour la déclaration à la CNIL.

15.2 Clinical study

- 5- SPRIET A., DUPIN-SPRIET T., SIMON P. Méthodologie des essais cliniques des médicaments
Basel : Karger; 3ème ed. 1993.

15.3 Investigational product(s)

- 1- Budzynski, T et al, Heart Rate Variability Enhancement Through Nanotechnology: A Double-Blind Randomized-Control Pilot Study, Journal of Neurotherapy, Vol. 12(1), pp 45-55, 2008.
- 2- Clark, D et al, Summary of IceWave Clinical Research Study – Infrared Imaging, <http://www.lifewave.com/research.asp>.
- 3 - Nazeran H, Chatlapalli S, Krishnam R “Effects of Novel Nanoscale Energy Patches on Spectral and Nonlinear Dynamic Features of Heart Rate Variability Signals in Healthy Individuals during Rest and Exercise”, Proceedings of the IEEE-Engineering in Medicine and Biology Society (EMBS), 27th Annual International Conference, Shanghai, China, September 1-4, 2005
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16 APPENDICES

16.1 General description of the study

16.1.1 Protocol and amendments

Not included.

16.1.2 Blank Case Report Form

Not included.

16.1.3 List of CPP (or IRB) with the name of the president if required by the competent authority

Not included.

16.1.4 Blank information and consent form

Not included.

16.1.5 List and identification of the investigators and important personal participating in the study

Name and address of the investigation sites	Name of the investigators of each center
<p>Center 1 : CMPR Iris 271 rue des Sources - BP 22 69280 Marcy-l'Etoile/ 25, rue André Lwoff 69800 Saint Priest/ 63 bis rue Maryse Bastié 69008 Lyon</p>	Dr Pierre Volckmann/ Dr Didier Lechemia
<p>Center 2 : CMPR du Bourget 7 rue Rigaud 93 350 Le Bourget</p>	Dr Emmanuel Chevillon/ Dr Didier Lechemia
<p>Center 3 : CSSR Choisy 9 bis rue Ledru Rollin 94 600 Choisy-le-Roi</p>	Dr Marc Pucheault/ Dr Didier Lechemia
<p>Center 4 : CMPR Rosemond 61-67 avenue des Goumiers 13 008 Marseille</p>	Dr Patrick Rolland/ Dr Didier Lechemia
<p>Center 5 : CMPR Le Floride, Avenue Thalassa 66421 Le Barcares</p>	Dr Jean Raynaud/ Dr Didier Lechemia
<p><u>Patch application on all centers :</u></p>	Thierry Garcia

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16.1.6 CV of the investigator(s)

Not included.

16.1.7 Signatures of the principal or coordinating investigator or of the sponsor medical representative

See page 2.

16.1.8 Listing of subjects receiving investigational product(s) from specific batches where more than one batch was used

Not applicable.

16.1.9 Randomisation scheme and codes (subject identification and treatment assigned)

Legend:

RDEYH36-FR: LifeWave Med pain relief 2-patch system

RDEYH38-FR: Placebo of 2-patch system

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Investigator centre	Screening number	Randomization number	Batch number
Lyon 8	01-701	01-201	RDEYH38-FR
Lyon 8	01-702	01-202	RDEYH36-FR
Lyon 8	01-703	01-203	RDEYH36-FR
Lyon 8	01-704	01-204	RDEYH38-FR
Marcy	01-721	01-221	RDEYH36-FR
Marcy	01-722	01-222	RDEYH36-FR
Marcy	01-723	01-223	RDEYH36-FR
Marcy	01-724	01-224	RDEYH36-FR
Marcy	01-725	01-225	RDEYH38-FR
Marcy	01-726	01-226	RDEYH38-FR
Marcy	01-727	01-227	RDEYH38-FR
Marcy	01-728	01-228	RDEYH36-FR
Marcy	01-729	01-229	RDEYH36-FR
Marcy	01-730	01-230	RDEYH38-FR
Marcy	01-731	01-231	RDEYH36-FR
Marcy	01-732	01-232	RDEYH36-FR
Marcy	01-733	01-233	RDEYH38-FR
Marcy	01-734	01-234	RDEYH36-FR
Marcy	01-735	01-235	RDEYH36-FR
Marcy	01-736	01-236	RDEYH38-FR
Marcy	01-737	01-237	RDEYH38-FR
Marcy	01-738	01-238	RDEYH36-FR
Marcy	01-739	01-239	RDEYH38-FR
Marcy	01-740	01-240	RDEYH36-FR
Marcy	01-741	01-241	RDEYH38-FR
Marcy	01-742	01-242	RDEYH36-FR
Marcy	01-743	01-243	RDEYH38-FR
Marcy	01-744	01-244	RDEYH38-FR
Marcy	01-745	01-245	RDEYH36-FR
Marcy	01-746	01-246	RDEYH36-FR
Marcy	01-747	01-247	RDEYH38-FR
Marcy	01-748	01-248	RDEYH38-FR
Marcy	01-749	01-249	RDEYH36-FR
Marcy	01-750	01-250	RDEYH36-FR
Marcy	01-751	01-251	RDEYH36-FR
Marcy	01-752	01-252	RDEYH38-FR
Marcy	01-753	01-253	RDEYH38-FR
St Priest	01-760	01-260	RDEYH36-FR
St Priest	01-761	01-261	RDEYH36-FR
St Priest	01-762	01-262	RDEYH38-FR
St Priest	01-763	01-263	RDEYH38-FR
St Priest	01-764	01-264	RDEYH36-FR
St Priest	01-765	01-265	RDEYH38-FR
St Priest	01-766	01-266	RDEYH38-FR
St Priest	01-767	01-267	RDEYH38-FR
St Priest	01-768	01-268	RDEYH36-FR
St Priest	01-769	01-269	RDEYH38-FR
St Priest	01-770	01-270	RDEYH36-FR
St Priest	01-790	01-290	RDEYH38-FR
St Priest	01-791	01-291	RDEYH38-FR
St Priest	01-792	01-292	RDEYH38-FR
St Priest	01-793	01-293	RDEYH36-FR
St Priest	01-794	01-294	RDEYH36-FR
St Priest	01-795	01-295	RDEYH36-FR
St Priest	01-796	01-296	RDEYH36-FR
St Priest	01-797	01-297	RDEYH36-FR
St Priest	01-798	01-298	RDEYH36-FR

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Investigator centre	Screening number	Randomization number	Batch number
St Priest	01-799	01-299	RDEYH36-FR
Lyon 8ème	01-820	01-320	RDEYH38-FR
Lyon 8ème	01-821	01-321	RDEYH38-FR
Lyon 8ème	01-822	01-322	RDEYH38-FR
Lyon 8ème	01-823	01-323	RDEYH36-FR
Lyon 8ème	01-824	01-324	RDEYH38-FR
Lyon 8ème	01-825	01-325	RDEYH38-FR
Lyon 8ème	01-826	01-326	RDEYH38-FR
Lyon 8ème	01-827	01-327	RDEYH38-FR
Lyon 8ème	01-828	01-328	RDEYH38-FR
Lyon 8ème	01-829	01-329	RDEYH38-FR
Lyon 8ème	01-830	01-330	RDEYH38-FR
Lyon 8ème	01-831	01-331	RDEYH36-FR
Lyon 8ème	01-832	01-332	RDEYH38-FR
Lyon 8ème	01-833	01-333	RDEYH36-FR
Lyon 8ème	01-834	01-334	RDEYH36-FR
Lyon 8ème	01-835	01-335	RDEYH36-FR
Marcy	01-840	01-340	RDEYH38-FR
Marcy	01-841	01-341	RDEYH36-FR
Marcy	01-842	01-342	RDEYH38-FR
Marcy	01-843	01-343	RDEYH36-FR
Marcy	01-844	01-344	RDEYH36-FR
Marcy	01-845	01-345	RDEYH36-FR
Marcy	01-846	01-346	RDEYH38-FR
Marcy	01-847	01-347	RDEYH36-FR
Marcy	01-849	01-349	RDEYH38-FR
Marcy	01-850	01-350	RDEYH36-FR
Marcy	01-851	01-351	RDEYH38-FR
Marcy	01-852	01-352	RDEYH38-FR
Marcy	01-853	01-353	RDEYH36-FR
Marcy	01-854	01-354	RDEYH38-FR
Marcy	01-855	01-355	RDEYH38-FR
Marcy	01-856	01-356	RDEYH36-FR
Marseille	04-702	04-102	RDEYH38-FR
Marseille	04-703	04-103	RDEYH38-FR
Marseille	04-704	04-104	RDEYH36-FR
Marseille	04-705	04-105	RDEYH38-FR
Marseille	04-706	04-106	RDEYH36-FR
Marseille	04-707	04-107	RDEYH36-FR
Marseille	04-708	04-108	RDEYH36-FR
Marseille	04-709	04-109	RDEYH38-FR
Marseille	04-710	04-110	RDEYH38-FR
Marseille	04-711	04-111	RDEYH36-FR

16.1.10 Audit certificates (if available)

Not applicable.

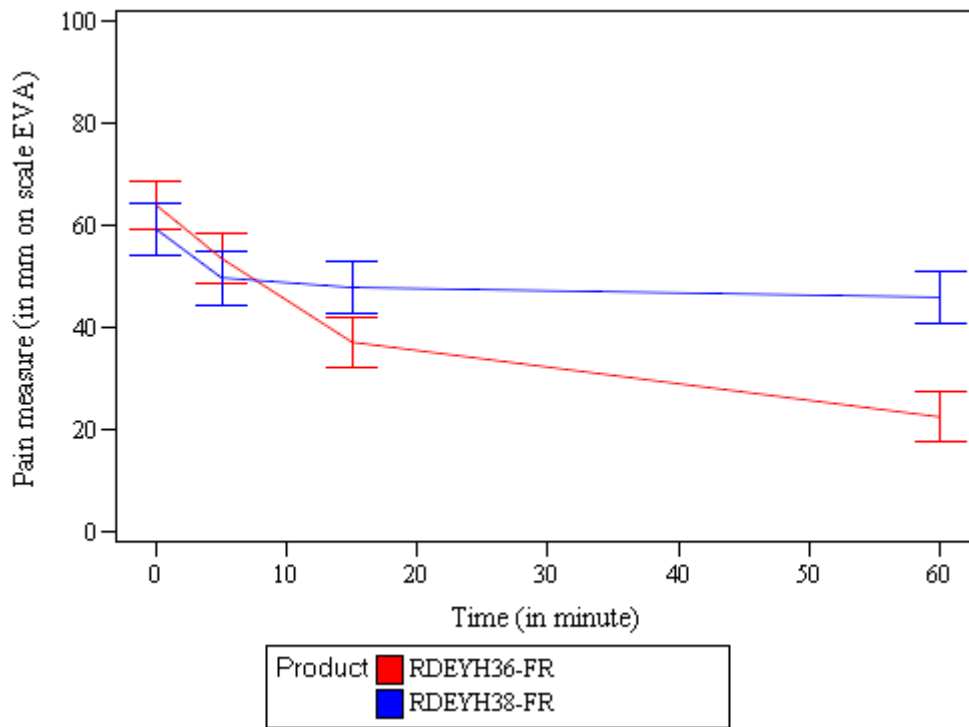
16.1.11 Documentation of statistical methods (statistical report)

16.1.11.1 Absolute change (ti-t0)

16.1.11.1.1 Descriptive statistics

Below the graph shows the evolution of the average measure of pain (in mm, on the scale EVA) over time for both products.

Evolution of pain over time



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Below, the table shows the descriptive statistics for the pain reduction (in mm) assessed with scale EVA at each time point $(t_i)_{i=0, 5min, 15min \text{ and } 1h}$ and for each changes $(t_i-t_0)_{i=5min, 15min \text{ and } 1h}$, for product “RDEYH36-FR” and product “RDEYH38-FR”.

Evolution of pain over time

Product	Variable	Mean	Std Dev	SEM	Median	Minimum	Maximum
RDEYH36-FR	Pain_T0	64.0	13.9	2.0	60.0	50.0	100.0
	Pain_T5min	53.6	18.5	2.6	55.0	20.0	100.0
	Pain_T15min	37.2	16.7	2.4	40.0	0.0	80.0
	Pain_T1h	22.6	19.2	2.7	20.0	0.0	80.0
	Pain_T5min_T0	-10.4	12.1	1.7	-10.0	-50.0	0.0
	Pain_T15min_T0	-26.8	14.1	2.0	-30.0	-60.0	0.0
	Pain_T1h_T0	-41.4	19.9	2.8	-40.0	-85.0	0.0
RDEYH38-FR	Pain_T0	59.3	11.9	1.7	52.5	50.0	90.0
	Pain_T5min	49.8	16.8	2.4	50.0	10.0	90.0
	Pain_T15min	47.9	20.1	2.8	50.0	0.0	100.0
	Pain_T1h	46.0	23.3	3.3	50.0	0.0	100.0
	Pain_T5min_T0	-9.5	12.4	1.8	0.0	-40.0	0.0
	Pain_T15min_T0	-11.4	15.7	2.2	-5.0	-50.0	10.0
	Pain_T1h_T0	-13.3	19.3	2.7	0.0	-60.0	10.0

16.1.11.2 Product difference on $(t_i-t_0)_{i=5min, 15min \text{ and } 1h}$ against value 15

Below, the table summarizes the comparison between the products difference against value 15 for each change (T_i-T_0) .

Difference between products against value 15

Comparison	change	Mean	SEM	p-value
RDEYH36-FR versus RDEYH38-FR	T5im-T0	-9.4467	3.3043	0.9525
	T15min-T0	-14.2733	3.3923	0.5847
	T1h-T0	-21.5333	3.4139	0.0288°

°: p-value obtained from one-tailed unpaired t-test against value (-15)

At 1h from baseline (T0), the data showed that the difference between both products (-21.53 ± 21) in terms of reduction of pain was significantly higher than 15 ($p=0.0288$) There was a higher improvement in terms of reduction of pain under product “RDEYH36-FR” than under “RDEYH38-FR”.

16.1.11.3 Change from baseline within each product group

Below, the table presents the comparison between each time point $(t_i)_{i=5min, 15min \text{ and } 1h}$ and baseline, on the estimated means, for each product.

Absolute change of pain

Product	Change	Estimate*	SEM*	DF	t Value	p-value [§]
RDEYH36-FR	t5min - t0	-10.4000	2.1515	29 4	-4.83	<.0001
	t15min - t0	-26.8000	2.1515	29 4	-12.46	<.0001
	t1h - t0	-41.4000	2.1515	29 4	-19.24	<.0001
RDEYH38-FR	t5min - t0	-9.5000	2.1515	29 4	-4.42	<.0001
	t15min - t0	-11.4000	2.1515	29 4	-5.30	<.0001
	t1h - t0	-13.3000	2.1515	29 4	-6.18	<.0001

§: contrasts from linear model for repeated measures

*: estimated from LS-Means

Whatever the product, the data showed a significant decrease in pain score (p<0.0001) on t5min, t15min and t1h in comparison with baseline (t0).

16.1.11.3.1 Comparison between products

Below, the table summarizes the comparison between the products, on the estimated means, in terms of absolute change from baseline (ti-t0).

Comparison of products on absolute change

Comparison	Change	Estimate*	SEM*	DF	t Value	Pr > t
RDEYH36-FR vs RDEYH38-FR	T5min-t0	-0.9000	3.0426	29 4	-0.30	0.7676
	T15min-t0	-15.4000	3.0426	29 4	-5.06	<.0001
	T1h-t0	-28.1000	3.0426	29 4	-9.24	<.0001

§: contrasts from linear model for repeated measures

*: estimated from LS-Means

The data showed a significant higher improvement of the pain with product “RDEYH36-FR” than with product “RDEYH38-FR” at t15min (-15.4±3, p<0.0001) and t1h (-28±3, p<0.0001).

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16.1.11.3.2 Proportion of subjects with a decrease of pain

Below, the table presents the proportion of subjects with a decrease of pain (on the scale EVA), at t5min, t5h and t1h from baseline (t0) under product.

Proportion of subjects with a decrease of pain

Variation	Decrease		RDEYH36-FR	RDEYH38-FR
T5min-T0	Yes	N	28	24
		%	56.00	48.00
	No	N	22	26
		%	44.00	52.00
p-value			0.4233	
T15min-T0	Yes	N	46	25
		%	92.00	50.00
	No	N	4	25
		%	8.00	50.00
p-value			<.0001	
T1h-T0	Yes	N	47	24
		%	94.00	48.00
	No	N	3	26
		%	6.00	52.00
p-value			<.0001	

*: Chi-square test

The data showed a significant more important proportion of subjects with a decrease of pain with product "RDEYH36-FR" than with product "RDEYH38-FR":

- At t15min, 46% versus 25% (p<0.0001)
- At t1h, 47% versus 24% (p<0.0001).

16.1.11.4 Relative change (in percent)

16.1.11.4.1 Change from baseline for within each group

Below, the table shows the descriptive statistics for the relative reduction of pain (in %) assessed with scale EVA at each time point (i)_{i=5min, 15min and 1h}, for product “RDEYH36-FR” and product “RDEYH38-FR”.

Relative change of pain (in %)

Product	Relative change (in %)	Estimate*	SEM*	DF	t Value	p-value [§]
RDEYH36-FR	(T5min - T0)/T0*100	-17.1452	3.6599	196	-4.68	<.0001
	(T15min - T0)/T0*100	-42.4365	3.6599	196	-11.59	<.0001
	(T1h - T0)/T0*100	-64.8730	3.6599	196	-17.73	<.0001
RDEYH38-FR	(T5min - T0)/T0*100	-16.3987	3.6599	196	-4.48	<.0001
	(T15min - T0)/T0*100	-20.0987	3.6599	196	-5.49	<.0001
	(T1h - T0)/T0*100	-23.4448	3.6599	196	-6.41	<.0001

§: contrasts from linear model for repeated measures

*: estimated from LS-Means

Whatever the product, the data showed a significant decrease (p<0.0001) at t5min, t15min and t1h in comparison with baseline (t0), in terms of relative change from baseline (in %).

At t1h, the percentage of pain decrease observed was:

- -65% for product “RDEYH36-FR”
- -23% for product “RDEYH38-FR”

16.1.11.4.2 Comparison between products

Below, the table summarizes the comparison between the products, on the estimated means, in terms of relative change from baseline (in %).

Comparison of products on relative change (in %)

Comparison		Estimate*	SEM*	DF	t Value	Pr > t
RDEYH36-FR vs RDEYH38-FR	(T5min - T0)/T0*100	-0.7465	5.1759	196	-0.14	0.8855
	(T15min - T0)/T0*100	-22.3378	5.1759	196	-4.32	<.0001
	(T1h - T0)/T0*100	-41.4282	5.1759	196	-8.00	<.0001

§: contrasts from linear model for repeated measures

*: estimated from LS-Means

The data analysis showed a significant higher pain reduction from baseline (t0) with product “RDEYH36-FR” than with product “RDEYH38-FR” 15 minutes (-22%±5, p<0.0001) and 1 hour (-41%±5, p<0.0001) after the patch application.

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16.1.12 Documentation of inter-laboratory standardisation methods and quality assurance procedures if used

Not applicable.

16.1.13 Publications based on the study

Not applicable.

16.2 Subject data listings

16.2.1 Discontinued subjects

See paragraph 10.1 of the report.

16.2.2 Protocol deviations

See paragraph 10.2 of the report.

16.2.3 Patients excluded from the efficacy analysis

See paragraph 10.2 of the report.

16.2.4 Demographic data

16.2.4.1 General subject characteristics

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LifeWave Med pain relief 2-patch system

Investigator centre	Screening number	Randomization number	Product	Subject initials	Age	Height (in m)	Weight (in kg)	PAS (in mm Hg)	PAD (in mm Hg)	Pulse rate (in bpm/min)	Sex	Origin of the pain treated by the patches		
Lyon 8	01-702	01-202	RDEYH36-FR	FP	63	1,60	59	130	70	70	F	surgery		
Lyon 8	01-703	01-203	RDEYH36-FR	BA	67	1,79	118	120	80	70	M	surgery		
Marcy	01-721	01-221	RDEYH36-FR	LC	65	1,72	78	130	70	75	M	arthrosis		
Marcy	01-722	01-222	RDEYH36-FR	CM	39	1,72	65	110	60	70	F	arthrosis		
Marcy	01-723	01-223	RDEYH36-FR	RM	53	1,78	103	150	80	75	M	arthrosis		
Marcy	01-724	01-224	RDEYH36-FR	MM	65	1,67	64	120	70	70	F	arthrosis		
Marcy	01-728	01-228	RDEYH36-FR	DP	54	1,68	71	100	70	70	F	arthrosis		
Marcy	01-729	01-229	RDEYH36-FR	BM	61	1,63	53,5	130	70	70	F	arthrosis		
Marcy	01-731	01-231	RDEYH36-FR	MG	63	1,72	72,5	120	80	70	M	surgery		
Marcy	01-732	01-232	RDEYH36-FR	FJ	60	1,68	67	120	70	70	M	traumatology		
Marcy	01-734	01-234	RDEYH36-FR	VM	55	1,63	78	130	80	70	F	surgery		
Marcy	01-735	01-235	RDEYH36-FR	GJ	67	1,65	83	130	70	70	M	arthrosis		
Marcy	01-738	01-238	RDEYH36-FR	GP	61	1,83	93	130	70	80	M	arthrosis		
Marcy	01-740	01-240	RDEYH36-FR	BM	52	1,68	82	110	60	70	M	traumatology		
Marcy	01-742	01-242	RDEYH36-FR	PP	65	1,65	47	120	70	70	F	arthrosis		
Marcy	01-745	01-245	RDEYH36-FR	GR	67	1,75	82	130	70	70	M	arthrosis		
Marcy	01-746	01-246	RDEYH36-FR	GM	68	1,50	48	130	80	75	F	arthrosis		
Marcy	01-749	01-249	RDEYH36-FR	LA	62	1,66	55	120	70	70	F	arthrosis		
Marcy	01-750	01-250	RDEYH36-FR	FC	52	1,67	49	120	80	70	F	traumatology		
Marcy	01-751	01-251	RDEYH36-FR	LE	65	1,67	70	140	70	70	F	arthrosis		
St Priest	01-760	01-260	RDEYH36-FR	FE	70	1,64	79	140	70	70	F	traumatology		
St Priest	01-761	01-261	RDEYH36-FR	VP	70	1,80	92	130	70	75	M	surgery		
St Priest	01-764	01-264	RDEYH36-FR	MS	59	1,60	88	125	70	75	F	surgery		
St Priest	01-768	01-268	RDEYH36-FR	RE	45	1,65	66	110	60	70	F	arthrosis		
St Priest	01-770	01-270	RDEYH36-FR	VF	50	1,63	61	130	80	70	F	arthrosis		
St Priest	01-793	01-293	RDEYH36-FR	MS	32	1,70	72	110	60	70	F	traumatology		
St Priest	01-794	01-294	RDEYH36-FR	RP	60	1,56	100	125	70	70	F	surgery		
St Priest	01-795	01-295	RDEYH36-FR	CM	64	1,70	60	110	60	70	F	arthrosis		
St Priest	01-796	01-296	RDEYH36-FR	VN	52	1,60	58	120	70	70	F	arthrosis		
St Priest	01-797	01-297	RDEYH36-FR	BC	54	1,65	61	120	70	70	F	arthrosis		
St Priest	01-798	01-298	RDEYH36-FR	MJ	65	1,55	43	150	80	75	F	arthrosis		
St Priest	01-799	01-299	RDEYH36-FR	CJ	70	1,60	49	120	70	70	F	arthrosis		
Lyon 8ème	01-823	01-323	RDEYH36-FR	NM	64	1,58	58,5	130	80	70	F	arthrosis		
Lyon 8ème	01-831	01-331	RDEYH36-FR	GY	70	1,62	65	130	70	70	F	arthrosis		
Lyon 8ème	01-833	01-333	RDEYH36-FR	BS	64	1,64	54	130	70	70	F	arthrosis		
Lyon 8ème	01-834	01-334	RDEYH36-FR	TJ	68	1,82	86	130	80	70	M	arthrosis		
Lyon 8ème	01-835	01-335	RDEYH36-FR	JJ	67	1,59	70	130	80	70	F	arthrosis		
Marcy	01-841	01-341	RDEYH36-FR	BV	31	1,74	59	110	60	70	F	traumatology		
Marcy	01-843	01-343	RDEYH36-FR	GJ	70	1,64	98	150	80	80	F	arthrosis		
Marcy	01-844	01-344	RDEYH36-FR	MD	41	1,74	68	110	60	70	M	arthrosis		
Marcy	01-845	01-345	RDEYH36-FR	GC	57	1,67	50	120	60	70	F	arthrosis		
Marcy	01-847	01-347	RDEYH36-FR	DB	64	1,67	72	130	60	70	M	arthrosis		
Marcy	01-850	01-350	RDEYH36-FR	GP	70	1,75	77	140	70	70	M	surgery		
Marcy	01-853	01-353	RDEYH36-FR	YC	47	1,68	66	125	70	70	F	surgery		
Marcy	01-856	01-356	RDEYH36-FR	VC	48	1,62	50	120	70	70	F	arthrosis		
Marseille	04-704	04-104	RDEYH36-FR	BP	54	1,70	75	130	75	75	M	surgery		
Marseille	04-706	04-106	RDEYH36-FR	SJ	62	1,57	79,5	120	70	70	F	arthrosis		
Marseille	04-707	04-107	RDEYH36-FR	GJ	68	1,66	75	140	80	75	M	traumatology		
Marseille	04-708	04-108	RDEYH36-FR	DB	69	1,62	90	130	80	75	F	arthrosis		
Marseille	04-711	04-111	RDEYH36-FR	NJ	46	1,66	65	140	70	70	M	surgery		
				Mean	59	1,67	71	126	71	71	F	33	arthrosis	32
				Median	63	1,66	69	130	70	70	M	17	surgery	11
				Minimum	31	1,50	43	100	60	70			traumatology	7
				Maximum	70	1,83	118	150	80	80				
				SEM	1	0,01	2	2	1	0,4				
				95% CI	3	0,02	5	3	2	1				

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Placebo of 2-patch system

Investigator centre	Screening number	Randomization number	Product	Subject initials	Age	Height (in m)	Weight (in kg)	PAS (in mm Hg)	PAD (in mm Hg)	Pulse rate (in bpm/min)	Sex	Origin of the pain treated by the patches		
Lyon 8	01-701	01-201	RDEYH38-FR	TJ	67	1,63	74	130	50	70	F	surgery		
Lyon 8	01-704	01-204	RDEYH38-FR	BS	58	1,60	68	120	70	70	F	surgery		
Marcy	01-725	01-225	RDEYH38-FR	TE	65	1,60	55	140	70	70	F	arthrosis		
Marcy	01-726	01-226	RDEYH38-FR	CH	69	1,60	55	140	70	75	F	arthrosis		
Marcy	01-727	01-227	RDEYH38-FR	SM	68	1,63	60	140	70	75	F	arthrosis		
Marcy	01-730	01-230	RDEYH38-FR	VM	45	1,58	79	140	70	75	F	arthrosis		
Marcy	01-733	01-233	RDEYH38-FR	TT	35	1,72	69	120	70	70	F	surgery		
Marcy	01-736	01-236	RDEYH38-FR	GL	67	1,59	73	140	90	80	F	surgery		
Marcy	01-737	01-237	RDEYH38-FR	CA	66	1,65	100	130	80	80	F	surgery		
Marcy	01-739	01-239	RDEYH38-FR	BN	65	1,76	84	120	70	70	M	surgery		
Marcy	01-741	01-241	RDEYH38-FR	BZ	68	1,58	84	140	80	75	F	arthrosis		
Marcy	01-743	01-243	RDEYH38-FR	DM	61	1,66	84	130	70	70	F	surgery		
Marcy	01-744	01-244	RDEYH38-FR	GY	69	1,56	64	130	70	75	F	traumatology		
Marcy	01-747	01-247	RDEYH38-FR	BC	69	1,70	75	130	70	70	F	arthrosis		
Marcy	01-748	01-248	RDEYH38-FR	RM	51	1,65	85	130	70	70	F	arthrosis		
Marcy	01-752	01-252	RDEYH38-FR	DV	44	1,68	64	120	70	70	F	arthrosis		
Marcy	01-753	01-253	RDEYH38-FR	PC	70	1,66	57	120	70	70	F	arthrosis		
St Priest	01-762	01-262	RDEYH38-FR	BA	70	1,58	88	130	70	70	F	arthrosis		
St Priest	01-763	01-263	RDEYH38-FR	GB	47	1,60	120	130	70	70	F	surgery		
St Priest	01-765	01-265	RDEYH38-FR	AM	49	1,67	88	140	70	80	M	arthrosis		
St Priest	01-766	01-266	RDEYH38-FR	RB	70	1,50	83	150	80	75	F	arthrosis		
St Priest	01-767	01-267	RDEYH38-FR	BJ	43	1,80	82	130	70	70	M	surgery		
St Priest	01-769	01-269	RDEYH38-FR	GH	64	1,60	63,5	150	80	90	F	traumatology		
St Priest	01-790	01-290	RDEYH38-FR	VJ	70	1,56	82	140	70	80	F	surgery		
St Priest	01-791	01-291	RDEYH38-FR	CA	69	1,53	57	130	75	75	F	arthrosis		
St Priest	01-792	01-292	RDEYH38-FR	OR	70	1,54	62	130	70	70	F	surgery		
Lyon 8ème	01-820	01-320	RDEYH38-FR	CC	51	1,69	58	120	70	70	F	surgery		
Lyon 8ème	01-821	01-321	RDEYH38-FR	FS	70	1,60	65	120	70	75	F	surgery		
Lyon 8ème	01-822	01-322	RDEYH38-FR	TA	61	1,62	57	140	80	75	F	surgery		
Lyon 8ème	01-824	01-324	RDEYH38-FR	GF	49	1,70	69	100	60	70	F	surgery		
Lyon 8ème	01-825	01-325	RDEYH38-FR	GM	67	1,53	46	120	70	70	F	surgery		
Lyon 8ème	01-826	01-326	RDEYH38-FR	VY	57	1,55	58	110	70	70	F	surgery		
Lyon 8ème	01-827	01-327	RDEYH38-FR	BB	59	1,75	105	140	80	70	M	arthrosis		
Lyon 8ème	01-828	01-328	RDEYH38-FR	BA	52	1,57	75	130	70	70	F	surgery		
Lyon 8ème	01-829	01-329	RDEYH38-FR	GS	64	1,65	60	100	60	70	F	arthrosis		
Lyon 8ème	01-830	01-330	RDEYH38-FR	LM	67	1,74	65	120	70	70	F	surgery		
Lyon 8ème	01-832	01-332	RDEYH38-FR	PG	70	1,61	57	110	60	70	F	arthrosis		
Marcy	01-840	01-340	RDEYH38-FR	MA	69	1,65	60	130	70	70	F	arthrosis		
Marcy	01-842	01-342	RDEYH38-FR	TY	62	1,56	72	110	60	70	F	traumatology		
Marcy	01-846	01-346	RDEYH38-FR	RC	33	1,65	60	110	60	60	F	surgery		
Marcy	01-849	01-349	RDEYH38-FR	VP	51	1,60	60	110	60	70	F	arthrosis		
Marcy	01-851	01-351	RDEYH38-FR	TR	53	1,74	67	110	50	70	F	arthrosis		
Marcy	01-852	01-352	RDEYH38-FR	TG	69	1,80	73	120	70	70	M	arthrosis		
Marcy	01-854	01-354	RDEYH38-FR	SJ	47	1,65	75	120	70	70	F	arthrosis		
Marcy	01-855	01-355	RDEYH38-FR	GG	53	1,68	87,5	140	70	80	F	surgery		
Marseille	04-702	04-102	RDEYH38-FR	ZS	57	1,77	98	120	70	70	M	surgery		
Marseille	04-703	04-103	RDEYH38-FR	ID	40	1,82	72	120	75	75	M	arthrosis		
Marseille	04-705	04-105	RDEYH38-FR	SK	31	1,70	55	110	60	60	M	traumatology		
Marseille	04-709	04-109	RDEYH38-FR	DM	48	1,70	77	120	70	75	M	surgery		
Marseille	04-710	04-110	RDEYH38-FR	BL	69	1,70	72	130	70	70	M	surgery		
				Mean	59	1,65	72	126	70	72	F	40	arthrosis	22
				Median	63	1,65	71	130	70	70	M	10	surgery	24
				Minimum	31	1,50	46	100	50	60			traumatology	4
				Maximum	70	1,82	120	150	90	90				
				SEM	2	0,01	2	2	1	1				
				95% CI	3	0,02	4	3	2	1				

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16.2.4.2 Medical history

Screening number	Randomisation #	Batch number	Description of the medical history	Date of beginning	Date of end or ongoing
01-701	01-201	RDEYH38-FR	RIGHT KNEE PROTHESIS	01/10/2010	01/10/2010
			LEFT KNEE PROTHESIS	09/04/2012	ONGOING
			HYPOTHYROIDISM	01/01/1992	ONGOING
			HYPERTENSION	01/01/2002	ONGOING
01-702	01-202	RDEYH36-FR	SURGERY OF RIGHT SHOULDER ROTATOR CUFF	01/01/2002	ONGOING
			SECOND SURGERY OF RIGHT SHOULDER ROTATOR CUFF	03/26/2012	ONGOING
			THIRD SURGERY OF RIGHT SHOULDER ROTATOR CUFF	07/07/2012	ONGOING
01-703	01-203	RDEYH36-FR	SURGERY OF RIGHT HUMERAL FRACTURE (HALF-PROTHESIS)	09/30/12	ONGOING
01-704	01-204	RDEYH38-FR	LEFT MASTECTOMY (CANCER)	01/01/2007	ONGOING
			LEFT HIP PROTHESIS	01/01/2008	01/01/2008
			RIGHT HIP PROTHESIS (FALL)	01/01/2009	ONGOING
			RIGHT SHOULDER PAIN (POST-FALL)	09/01/2012	ONGOING
01-721	01-221	RDEYH36-FR	NUCLEOUS PULPOSUS HERNIATION L5S1 SURGERY	01/01/1989	01/01/1989
			NUCLEOUS PULPOSUS HERNIATION L4L5 SURGERY	01/01/1989	01/01/1989
			DIFFUSE POLYARTHRITIS AND SEVERE LUMBAR SPONDYLOSIS	01/01/2000	ONGOING
			HYPOTHYROIDISM	01/01/2002	ONGOING
01-722	01-222	RDEYH36-FR	CERVICAL ARTHRITIS (HYPERALGESIA)	01/01/2010	ONGOING
01-723	01-223	RDEYH36-FR	CERVICAL ARTHRITIS	01/01/2002	ONGOING
			BILATERAL COXARTHROSIS	01/01/2009	ONGOING
			DISCOPATHY L4L5 AND L5S1 + LEFT NUCLEOUS PULPOSUS HERNIATION L5S1	01/09/2012	ONGOING
01-724	01-224	RDEYH36-FR	BILATERAL SHOULDER TENDINOPATHY + LEFT SHOULDER CAPSULITIS	06/01/2012	ONGOING
01-725	01-225	RDEYH38-FR	LEFT HIP PROTHESIS	03/12/2012	ONGOING
			HYPOTHYROIDISM	01/01/2011	ONGOING
			ROTATOR CUFF TENDINOPATHY	01/01/2012	ONGOING
01-726	01-226	RDEYH38-FR	RIGHT HIP PROTHESIS	12/03/2012	ONGOING
			LEFT HALLUX VALGUS SUGERY	01/01/2010	01/01/2010
			LEFT GLUTEAL TENDINITIS	12/01/2011	ONGOING
01-727	01-227	RDEYH38-FR	RIGHT HIP PROTHESIS	01/01/2008	01/01/2008
			RIGHT KNEE PROTHESIS	01/01/2009	01/01/2009
			SURGERY OF RIGHT ROTATOR CUFF	01/01/2010	01/01/2010
			LEFT KNEE PROTHESIS	01/01/2011	01/01/2011
			PARKINSON'S DISEASE	01/01/2008	ONGOING
			POLYARTHRITIS (CERVICAL ARTHRITIS)	01/01/2008	ONGOING
01-728	01-228	RDEYH36-FR	RIGHT ANKLE ARTHRITIS	01/01/2011	ONGOING
01-729	01-229	RDEYH36-FR	LEFT HIP COXARTHROSIS	02/01/2012	ONGOING
01-729	01-229	RDEYH36-FR	RIGHT CERVICOBACHIAL NEURALGIA (CERVICAL ARTHRITIS)	01/01/2010	ONGOING
01-730	01-230	RDEYH38-FR	HEART TRANSPLANT	01/01/2008	ONGOING
			HISTERECTOMY	01/01/2011	01/01/2011
			LEFT CRURALGIA	01/01/2011	ONGOING
			DIABETES	01/01/2008	ONGOING
			HYPERCHOLESTEROLEMIA	01/01/2008	ONGOING
			HYPERTENSION	01/01/2008	ONGOING
01-731	01-231	RDEYH36-FR	TOTAL LEFT KNEE PROTHESIS	01/11/2010	01/11/2010
			TOTAL RIGHT KNEE PROTHESIS	11/20/2012	ONGOING
			LEFT CRUCIATE KNEE LIGAMENT SURGERY	01/01/1981	01/01/1981
01-732	01-232	RDEYH36-FR	HEAD AND FACE TRAUMA (6 SURGERIES OF RIGHT HALF FACE) SEVERE ALGIA	08/21/03	ONGOING
01-733	01-233	RDEYH38-FR	LEFT AND RIGHT HALLUX VALGUS SUGERY	01/01/1997	ONGOING
			LEFT CRUCIATE KNEE LIGAMENT SURGERY	12/09/2012	ONGOING
01-734	01-234	RDEYH36-FR	TOTAL RIGHT MASTECTOMY (CANCER)	05/05/2010	05/05/2010
			RIGHT BREAST RECONSTRUCTION AND LEFT BREAST REDUCTION	12/03/2012	ONGOING
01-735	01-235	RDEYH36-FR	RIGHT GONARTHROSIS (HYPERALGIC)	01/01/2005	ONGOING
01-736	01-236	RDEYH38-FR	TOTAL RIGHT HIP PROTHESIS	12/03/2012	ONGOING
			HYPERTENSION	01/01/2003	ONGOING

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Screening number	Randomisation #	Batch number	Description of the medical history	Date of beginning	Date of end or ongoing
01-737	01-237	RDEYH38-FR	LEFT KNEE PROTHESIS	01/01/2008	01/01/2008
			RIGHT KNEE PROTHESIS	12/03/2012	ONGOING
			RHIZOMELIC POLYARTHRITIS	01/05/2012	ONGOING
01-738	01-238	RDEYH36-FR	RIGHT GONARTHROSIS (HYPERALGIC)	01/02/2011	ONGOING
			LEFT LUMBAR PAIN + LEFT SCIATICA	01/01/2012	ONGOING
01-739	01-239	RDEYH38-FR	LEFT KNEE PROTHESIS	12/03/2012	ONGOING
01-740	01-240	RDEYH36-FR	ACUTE LUMBAR PAIN (CAR ACCIDENT ON 2006)	01/01/2012	ONGOING
			CAR ACCIDENT (2006): PELVIS FRACTURE + SPLENECTOMY + LUMBAR AND THORACIC TRAUMA	01/01/2006	ONGOING
01-741	01-241	RDEYH38-FR	FRACTURE OF LEFT FEMORAL NECK	11/21/2012	ONGOING
			TUMORECTOMY OF LEFT BREAST	01/01/2011	01/01/2011
			RIGHT SHOULDER ARTHRITIS	09/01/2012	ONGOING
01-742	01-242	RDEYH36-FR	SEVERE ARTHRITIS LUMBAR (HYPERALGESIA)	11/15/2012	ONGOING
01-743	01-243	RDEYH38-FR	LEFT ANKLE PROTHESIS	09/18/2012	ONGOING
			RIGHT KNEE PROTHESIS	01/22/2013	
01-744	01-244	RDEYH38-FR	PAIN LUMBAR (FRACTURE OF L2)	03/27/2012	ONGOING
			HIATUS HERNIA	07/01/2010	07/01/2010
			HYPERTENSION	01/01/2003	ONGOING
01-745	01-245	RDEYH36-FR	RIGHT GONARTHROSIS (HYPERALGIC MENISCECTOMY)	01/01/1993	ONGOING
01-746	01-246	RDEYH36-FR	ATHRITIS AND RIGHT ELBOW TENDINOPATHY	12/01/2012	ONGOING
			HYPERTENSION	01/01/2008	
01-747	01-247	RDEYH38-FR	SEVERE CERVICAL ARTHRITIS	01/01/2013	ONGOING
			LEFT KNEE PROTHESIS	10/01/2006	10/01/2006
			HYPERTENSION	01/01/2002	ONGOING
			HYPERCHOLESTEROLEMIA	01/01/2002	
01-748	01-248	RDEYH38-FR	BILATERAL TIBIAL OSTEOTOMY	01/01/1983	01/01/1983
			BILATERAL HALLUX VALGUS SURGERY	01/01/2004	01/01/2004
			BILATERAL GONARTHROSIS	01/01/2006	ONGOING
01-749	01-249	RDEYH36-FR	RIGHT HIP TENDINITIS	09/01/2012	ONGOING
01-750	01-250	RDEYH36-FR	CERVICAL ARTHRITIS + CERVICOBRACHIAL NEURALGIA	01/01/2013	ONGOING
01-751	01-251	RDEYH36-FR	RIGHT SHOULDER ARTHRITIS	01/01/2010	ONGOING
			BILATERAL GONARTHROSIS	01/01/2010	ONGOING
			OSTEOPOROSIS	01/01/2010	ONGOING
01-752	01-252	RDEYH38-FR	BACK ARTHRITIS	01/01/2012	ONGOING
01-753	01-253	RDEYH38-FR	POLYARTHROPATY	01/01/1983	ONGOING
01-760	01-260	RDEYH36-FR	LEFT KNEE PROTHESIS	12/04/2012	ONGOING
			RIGHT KNEE PROTHESIS (1st)	01/01/2011	
			RIGHT KNEE PROTHESIS (2nde)	02/01/2012	
01-761	01-261	RDEYH36-FR	LEFT KNEE PROTHESIS	02/20/2013	ONGOING
			PROSTATIC RESECTION	01/01/2009	01/01/2009
			DIABETES	01/01/2001	ONGOING
01-762	01-262	RDEYH38-FR	RIGHT ANKLE FRACTURE : OSTEOSYNTHESIS	12/24/2012	ONGOING
			SEVERE CERVICAL ARTHRITIS	01/01/2000	
			BILATERAL PAINFUL SHOULDER (PERIARTHROSIS)	02/01/2013	
			RIGHT KNEE GONARTHROSIS	01/01/2011	
01-763	01-263	RDEYH38-FR	NARROW LUMBAR CANAL OPERATION + NUCLEUS PULPOSUS HERNIATION L4L5-L5S1 SURGERY	12/19/2007	12/19/2007
			RETURN OF NARROW LUMBAR CANAL OPERATION + NUCLEUS PULPOSUS HERNIATION L4L5-L5S1 ARTHRODESIS	12/20/2012	ONGOING
01-764	01-264	RDEYH36-FR	LUMBAR SPINE OSTEOSYNTHESIS + NARROW VERTEBRAL CANAL	02/12/2013	ONGOING
			DIABETES	01/01/1999	
			HYPERCHOLESTEROLEMIA		
01-765	01-265	RDEYH38-FR	CERVICAL ARTHRITIS	01/01/2013	ONGOING
01-766	01-266	RDEYH38-FR	RIGHT KNEE PROTHESIS	12/07/2012	ONGOING
			DIABETES	01/01/2005	
01-767	01-267	RDEYH38-FR	RIGHT PATELLA FRACTURE AND CRUCIATE KNEE LIGAMENTS SURGERY	01/25/2013	ONGOING

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01-768	01-268	RDEYH36-FR	RHEUMATOID ARTHRITIS	01/01/1998	ONGOING
01-769	01-269	RDEYH38-FR	SEVERE GIBBOSITY - VERTEBRAL COMPRESSION	01/01/2000	ONGOING
01-770	01-270	RDEYH36-FR	PAINFUL SHOULDER (PERIARTHROSIS)	11/01/2012	ONGOING
			CHRONIC DEPRESSION	01/01/2000	
01-790	01-290	RDEYH38-FR	RIGHT KNEE PROTHESIS	01/20/2013	ONGOING
			LEFT KNEE PROTHESIS	02/21/2012	02/21/2012
			CATARACT OPERATION	01/01/2012	01/01/2012
			HYPERTENSION	01/01/2000	ONGOING
			DIABETES	01/01/2005	
HYPERCHOLESTEROLEMIA	01/01/2005				
01-791	01-291	RDEYH38-FR	LEFT PAINFUL SHOULDER	01/25/2013	ONGOING
			HYPERTENSION	01/01/2009	
			HYPERCHOLESTEROLEMIA	01/01/2004	
01-792	01-292	RDEYH38-FR	NUCLEUS PULPOSUS HERNIATION L4L5 SURGERY	02/26/2013	ONGOING
			NUCLEUS PULPOSUS HERNIATION L5S1 SURGERY	01/01/1998	
			HYPOTHYROIDISM	01/01/2000	
			HYPERTENSION	01/01/2000	
01-793	01-293	RDEYH36-FR	MOTORBIKE ACCIDENT : RIGHT TIBIAL INTERCONDYLAR FRACTURE + RIGHT SHINBONE FRACTURE + CRUCIATE LIGAMENT RUPTURE	06/16/2012	ONGOING
01-794	01-294	RDEYH36-FR	LEFT KNEE PROTHESIS SURGERY	10/22/2012	ONGOING
			RIGHT KNEE PROTHESIS SURGERY	05/05/2012	05/05/2012
			DIABETES	01/01/1998	ONGOING
			HYPERTENSION	01/01/1998	ONGOING
01-795	01-295	RDEYH36-FR	SEVERE CERVICAL ARTHRITIS	01/01/2010	ONGOING
			HYPERTENSION	01/01/2000	
01-796	01-296	RDEYH36-FR	RHEUMATOID ARTHRITIS	01/01/2009	ONGOING
01-797	01-297	RDEYH36-FR	BONE MYELOMA (REMISSION)	04/01/2012	ONGOING
			LEFT RIBS FRACTURE	03/19/2013	
			DIFFUSE POLYARTHROPATHY	01/01/2010	
01-798	01-298	RDEYH36-FR	SEVERE POLYARTHROPATHY	01/01/2000	ONGOING
			MENINGIOMA IN D12 OPERATION	04/01/2000	
01-799	01-299	RDEYH36-FR	CERVICAL ARTHROSIS + LEFT CERVICOBACHIAL NEURALGIA	03/01/2013	ONGOING
			HYPERTENSION	01/01/2011	
01-820	01-320	RDEYH38-FR	SURGERY ON RIGHT CARPAL TUNNEL (RESIDUAL PAIN)	02/13/2007	ONGOING
			RIGHT DUPUYTREN SURGERY (RESIDUAL PAIN)	12/08/2009	ONGOING
01-821	01-321	RDEYH38-FR	LEFT HIP PROTHESIS	02/01/2011	02/01/2011
			RIGHT HIP PROTHESIS	02/28/2013	ONGOING
			ANEURYSM OPERATION	12/11/2007	12/11/2007
01-822	01-322	RDEYH38-FR	SURGERY OF RIGHT SHOULDER ROTATOR CUFF	01/03/2013	ONGOING
01-823	01-323	RDEYH36-FR	SEVERE CERVICAL ARTHRITIS	01/01/2000	ONGOING
			HYPERTENSION	01/01/2011	
01-824	01-324	RDEYH38-FR	LEFT HAND TENDON RUPTURE AND FRACTURE OPERATION (AFTER-EFFECTS PAIN)	11/07/2012	ONGOING
			LEFT FOOT MULTIPLE FRACTURE (AFTER-EFFECTS PAIN)	07/28/2012	
01-825	01-325	RDEYH38-FR	RIGHT KNEE PROTHESIS	03/05/2013	ONGOING
			RIGHT LEG OSTECTOMY	01/01/2001	01/01/2001
			LEFT HIP PROTHESIS	01/01/2002	01/01/2002
			RIGHT ANKLE PAIN (ARTHRITIS) SINCE RIGHT KNEE PTOHESIS	03/05/2013	ONGOING
01-826	01-326	RDEYH38-FR	LEFT SHOULDER TENDON OPERATION	01/29/2013	ONGOING
			HYPERCHOLESTEROLEMIA	10/01/2012	
01-827	01-327	RDEYH38-FR	SURGERY OF RIGHT THIGHBONE FRACTURE	11/10/2012	ONGOING
			RIGHT KNEE PROTHESIS	01/01/2010	01/01/2010
			DIABETES	01/01/1998	ONGOING
			LUMBAGO	11/10/2012	ONGOING
01-828	01-328	RDEYH38-FR	RIGHT KNEE PROTHESIS	03/28/2013	ONGOING
			GASTRITIS ULCER	04/02/2013	
01-829	01-329	RDEYH38-FR	RIGHT FOOT FRACTURE	01/16/2013	ONGOING
			OPERATED RIGHT ELBOW FRACTURE		
01-830	01-330	RDEYH38-FR	LEFT KNEE TOTAL PROTHESIS	03/13/2013	ONGOING
			RIGHT GONARTHROSIS	01/01/2010	

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01-831	01-331	RDEYH36-FR	CERVICODORSAL ARTHRITIS (INVALIDATING)	01/01/1990	ONGOING
01-832	01-332	RDEYH38-FR	HAND ARTHRITIS + RIGHT THUMB ARTHRITIS	01/01/2013	ONGOING
01-833	01-333	RDEYH36-FR	RHIZOMELIC POLYARTHRITIS	01/01/2008	ONGOING
			LUMBAR SPONDYLOSIS	01/01/2000	
			HYPERTENSION	01/01/2008	
01-834	01-334	RDEYH36-FR	BILATERAL SHOULDER ARTHRITIS	01/01/2012	ONGOING
			HYPERTENSION	01/01/2003	
01-835	01-335	RDEYH36-FR	POLYARTHROPATHY	01/01/2000	ONGOING
01-840	01-340	RDEYH38-FR	LEFT KNEE PROTHESIS	03/23/2013	ONGOING
			RIGHT GONARTHROSIS	01/01/2000	
			L5 COLLAPSING	11/01/2012	
			HYPERTENSION	01/01/2005	
01-841	01-341	RDEYH36-FR	CERVICAL TRAUMA	01/01/2013	ONGOING
01-842	01-342	RDEYH38-FR	RIGHT HIP TOTAL PROTHESIS	01/01/2006	ONGOING
			TRAUMA WITH PROTHESIS ACETABULUM FRACTURE	12/18/2012	
			RIGHT BOTTOM PAIN	12/18/2012	
			LEFT UPPER LIMB PAIN	12/18/2012	
01-843	01-343	RDEYH36-FR	SEVERE LUMBAR ARTHRITIS	01/01/2012	ONGOING
			ARTHRITIS	01/01/2000	
01-844	01-344	RDEYH36-FR	NUCLEUS PULPOSUS HERNIATION L5-S1	01/01/2005	ONGOING
			THREE BYPASS	03/22/2013	
01-845	01-345	RDEYH36-FR	SPLENECTOMY	01/01/1987	01/01/1987
			THYROIDECTOMY	01/01/2007	
			POLYARTHROPATHY	01/01/20110	
			RIGHT KNEE FRACTURE OSTEOSYNTHESIS	03/12/2013	
01-846	01-346	RDEYH38-FR	RIGHT KNEE FRACTURE OSTEOSYNTHESIS	03/12/2013	ONGOING
01-847	01-347	RDEYH36-FR	LEFT CRURALGIA (PAIN)	04/08/2013	ONGOING
01-849	01-349	RDEYH38-FR	CERVICAL ARTHRITIS	01/01/2010	ONGOING
			HYPOTHYROIDISM	01/01/1991	
01-850	01-350	RDEYH36-FR	RIGHT KNEE TOTAL PROTHESIS	02/22/2013	ONGOING
			HYPERTENSION	01/01/2010	
01-851	01-351	RDEYH38-FR	CEREBROVASCULAR NEUROLOGIC DISEASE WITH UPPER LIMB PARALYSIS	02/03/2013	ONGOING
			LEFT SHOULDER PAIN	03/03/2013	
01-852	01-352	RDEYH38-FR	PROSTATECTOMY	01/01/2003	ONGOING
			LEFT HEMIPLEGIA CEREBROVASCULAR NEUROLOGIC DISEASE - LEFT SHOULDER PAIN	11/01/2012	
01-853	01-353	RDEYH36-FR	LEFT BREAST TUMORECTOMY	02/08/2012	ONGOING
			LEFT SHOULDER PAIN	02/08/2012	
01-854	01-354	RDEYH38-FR	LUMBAGO	01/01/2005	ONGOING
01-855	01-355	RDEYH38-FR	RIGHT HIP PROTHESIS SURGERY	01/01/2007	ONGOING
			LEFT HIP PROTHESIS SURGERY	03/01/2013	
			HYPERTENSION	01/01/2010	
01-856	01-356	RDEYH36-FR	NUCLEUS PULPOSUS HERNIATION L5-S1	01/01/2013	ONGOING
04-702	04-102	RDEYH38-FR	LEFT KNEE PROTHESIS	01/01/2010	ONGOING
			RIGHT KNEE PROTHESIS	10/22/2012	
04-703	04-103	RDEYH38-FR	FIBROMYALGIA	01/01/2012	ONGOING
			DIFFUSE POLYARTHROPATHY	01/01/2002	
04-704	04-104	RDEYH36-FR	NUCLEUS PULPOSUS HERNIATION L4L5 SURGERY	11/09/2012	11/09/2012
04-705	04-105	RDEYH38-FR	THIGH BONE FRACTURE SURGERY	09/22/2012	09/22/2012
			SCIATICA PAIN		ONGOING
04-706	04-106	RDEYH36-FR	POLYARTHROPATHY	01/01/1970	ONGOING
			LEFT HAND ARTHRITIS	01/01/2002	
			NUCLEUS PULPOSUS HERNIATIONS L3L4,L5-S1 SURGERY	11/06/2012	
04-707	04-107	RDEYH36-FR	RIGHT LEG TIBIA-FIBULA SUGERY	05/01/2012	05/01/2012
			LEFT SHOULDER ROTATOR CUFF LESION	01/01/2000	ONGOING
04-708	04-108	RDEYH36-FR	NARROW LUMBAR CANAL OPERATION	11/27/2012	11/27/2012
			POLYARTHROPATHY	01/01/1990	ONGOING
04-709	04-109	RDEYH38-FR	NUCLEUS PULPOSUS HERNIATION L5-S1 SURGERY	11/02/2012	11/02/2012
04-710	04-110	RDEYH38-FR	LEFT HIP PROTHESIS	09/25/2012	09/25/2012
			RIGHT HIP PROTHESIS	03/07/2003	03/07/2003
			RIGHT KNEE PROTHESIS	01/01/2008	01/01/2008
04-711	04-111	RDEYH36-FR	NUCLEUS PULPOSUS HERNIATIONS L4L5 L5-S1 SURGERY	11/14/2012	11/14/2012

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16.2.4.3 Previous treatments

Screening number	Randomisation #	Batch number	Previous or concomitant treatment at the inclusion					Date of beginning	Date of end or ongoing
			Treatment	Indication	Posology	Administration route			
01-701	01-201	RDEYH38-FR	VOLTARENE LP 100	PAIN	1/D	ORAL	09/04/2012	ONGOING	
			LEVOTHYROX	HYPERTHYROIDISM			01/01/2012		
			HYTACAND	HYPERTENSION			01/01/2002		
01-702	01-202	RDEYH36-FR	DAFALGAN CODEINE	PAIN	6/D	ORAL	07/07/2012	ONGOING	
01-703	01-203	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	09/30/2012	ONGOING	
			TOPALGIC 100 mg						
01-704	01-204	RDEYH38-FR	TOPALGIC 100 mg	PAIN	2/D	ORAL	09/01/2012	ONGOING	
			MYOLASTAN						
01-721	01-221	RDEYH36-FR	LEVOTHYROX 75	HYPERTHYROIDISM	1/D	ORAL	01/01/2002	ONGOING	
			DOLIPRANE 1000	PAIN	3/D		10/01/2012		
			VOLTARENE LP 100	PAIN	1/D				
01-722	01-222	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2010	ONGOING	
			TOPALGIC		2/D		12/01/2012		
			VOLTARENE LP 100		1/D				
01-723	01-223	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	09/01/2012	ONGOING	
			ART 50	PAIN - ARTHROSIS	2/D		01/01/2011		
			CHONDROSULF	PAIN - ARTHROSIS	3/D		01/01/2011		
			TOPALGIC	PAIN	2/D		09/01/2012		
			VOLTARENE LP 100	PAIN	2/D		09/01/2012		
01-724	01-224	RDEYH36-FR	DOLIPRANE 1000	PAIN	2/D	ORAL	06/01/2012	ONGOING	
			BIPROFENID		1/D		09/01/2012		
			LAROXYL DROPS		10/D		10/01/2012		
01-725	01-225	RDEYH38-FR	LEVOTHYROX	HYPOTHYROIDISM	1/D	ORAL	01/01/2011	ONGOING	
01-726	01-226	RDEYH38-FR	DAFALGAN 1000	PAIN	1/D	ORAL	09/01/2010	ONGOING	
			BIPROFENID				12/03/2012		
01-727	01-227	RDEYH38-FR	CHONDROSULF	ARTHROSIS	3/D	ORAL	01/01/2008	ONGOING	
			GINKOR	VENOUS INSUFFICIENCY	2/D		01/01/2000		
			MODOPAR	PARKINSON	5/D		01/01/2008		
			REQUIP	PARKINSON	1/D		01/01/2008		
			DAFALGAN 1000	PAIN	3/D		01/01/2012		
01-728	01-228	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2011	ONGOING	
			BIPROFENID		1/D		12/01/2012		
01-729	01-229	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2010	ONGOING	
			VOLTARENE LP 100	PAIN	1/D		12/01/2012		
			MYOLASTAN	MUSCLES CONTRACTION	1/D		12/01/2012		
01-730	01-230	RDEYH38-FR	METFORMINE 500	DIABETES	2/D	ORAL	01/01/2008	ONGOING	
			JANUVIA	DIABETES	1/D		01/01/2008		
			PROGRAF	AGAINST REJECTION FOR	5/D		01/01/2008		
			MIFORTIK 360	AGAINST REJECTION FOR	2/D		01/01/2008		
			EZETROL	HYPERCHOLESTEROLEMIA	1/D		01/01/2008		
			TAHOR 20	HYPERCHOLESTEROLEMIA	1/D		01/01/2008		
			TAREG 80	HYPERTENSION	1/D		01/01/2008		
01-731	01-231	RDEYH36-FR	TOPALGIC 100	PAIN	2/D	ORAL	11/20/2012	ONGOING	
			BIPROFENID	PAIN	1/D		11/20/2012		
			MYOLASTAN	MUSCLES CONTRACTION	1/D		11/20/2012		
01-732	01-232	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	08/21/2003	ONGOING	
			LYRICA		3/D		01/01/2012		
			RIVOTRIL		1/D		01/01/2010		
01-733	01-233	RDEYH38-FR	BIPROFENID 100	PAIN	2/D	ORAL	12/09/2012	ONGOING	
			TETRAZEPAM	MUSCLES CONTRACTION	2/D		12/09/2012		
			LYRICA 25	PAIN	2/D		12/09/2012		
01-734	01-234	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	12/03/2012	ONGOING	
			TOPALGIC	PAIN	2/D		12/03/2012		
			TAMOXIFENE	BREAST CANCER	1/D		05/05/2010		
01-735	01-235	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	12/01/2012	ONGOING	
			BIPROFENID LP 100		1/D		12/01/2012		
01-736	01-236	RDEYH38-FR	TOPALGIC	PAIN	2/D	ORAL	12/01/2012	ONGOING	
			HYPERIUM	HYPERTENSION	1/D		01/01/2003		
			COOLMETEC	HYPERTENSION	1/D		01/01/2003		
			TEMERIT	HYPERTENSION	1/D		01/01/2003		
01-737	01-237	RDEYH38-FR	PREDNISOLONE	POLYARTHROSIS	1/D	ORAL	01/05/2012	ONGOING	
			DOLIPRANE 1000	PAIN	3/D		12/03/2012		
			TRAMADOL	PAIN	1/D		12/03/2012		
01-738	01-238	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/02/2011	ONGOING	
			BIPROFENID LP 100		1/D		01/01/2012		
01-739	01-239	RDEYH38-FR	DAFALGAN 1000	PAIN	4/D	ORAL	12/03/2012	ONGOING	
			BIPROFENID		2/D		12/03/2012		
			TOPALGIC		2/D		12/03/2012		
			ACUPAN		2/D		12/03/2012		
01-740	01-240	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2012	ONGOING	
			BIPROFENID		2/D		12/01/2012		
			TOPALGIC		1/D		12/01/2012		

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Screening number	Randomisation #	Batch number	Previous or concomitant treatment at the inclusion					
			Treatment	Indication	Posology	Administration route	Date of beginning	Date of end or ongoing
01-741	01-241	RDEYH38-FR	DOLIPRANE TOPALGIC	PAIN	3/D	ORAL	09/01/2012	ONGOING
01-742	01-242	RDEYH36-FR	DAFALGAN CODEINE BIPROFENID	PAIN	2/D	ORAL	11/15/2012	ONGOING
01-743	01-243	RDEYH38-FR	SEROPLEX 10	DEPRESSION	1/D	ORAL	01/01/2013	ONGOING
			STABLON		3/D		01/01/2009	
			XANAX 0,25	ANXIETY	3/D			
			STILNOX	INSOMNIA	1/D			
			BIPROFENID CP 100 TOPALGIC	PAIN	1/D 2/D		01/01/2013	
			DOLIPRANE 1000		4/D			
01-744	01-244	RDEYH38-FR	DOLIPRANE 1000 APROVEL 75	PAIN HYPERTENSION	2/D 1/D	ORAL	03/27/2012 01/01/2003	ONGOING
01-745	01-245	RDEYH36-FR	DOLIPRANE 1000 IBUPROFENE	PAIN	2/D	ORAL	01/01/2013 01/01/2013	ONGOING
01-746	01-246	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	12/01/2012	ONGOING
			IBUPROFENE				02/01/2013	
			HYTACAND 8	HYPERTENSION	1/D		01/01/2008	
01-747	01-247	RDEYH38-FR	EFFERALGAN 1000	PAIN	3/D	ORAL	01/01/2013	ONGOING
			VOLTARENE LP 100		1/D		02/01/2013	
			LODOZ	HYPERTENSION	1/D		01/01/2002	
			ELISOR 20	HYPERCHOLESTEROLEMIA	1/D		01/01/2002	
01-748	01-248	RDEYH38-FR	PARACETAMOL 1000 IBUPROFENE	PAIN	3/D	ORAL	01/01/2006 01/01/2013	ONGOING
01-749	01-249	RDEYH36-FR	DOLIPRANE 1000 APRANAX	PAIN	3/D 1/D	ORAL	09/01/2012 02/01/2013	ONGOING
01-750	01-250	RDEYH36-FR	PARACETAMOL 1000	PAIN	3/D	ORAL	01/01/2013	ONGOING
01-751	01-251	RDEYH36-FR	ACTONEL	OSTEOPOROSIS	1/D	ORAL	01/01/2010	ONGOING
			OROCAL D3					
			IBUPROFENE 400	PAIN	3/D		01/01/2013	
			EFFERALGAN 1000		2/D			
01-752	01-252	RDEYH38-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2012	ONGOING
01-753	01-253	RDEYH38-FR	IXPRIM	PAIN	1/D	ORAL	02/01/2013	ONGOING
01-753	01-253	RDEYH38-FR	EFFERALGAN 1000	PAIN	3/D	ORAL	01/01/2010	ONGOING
01-760	01-260	RDEYH36-FR	LAMALINE TAHOR 10	PAIN HYPERCHOLESTEROLEMIA	3/D 1/D	ORAL	12/04/2012 01/01/2010	ONGOING
01-761	01-261	RDEYH36-FR	DOLIPRANE 1000 METFORMINE 500	PAIN DIABETES	3/D NK	ORAL	02/20/2013 01/01/2001	ONGOING
01-762	01-262	RDEYH38-FR	DOLIPRANE 1000 FLECTOR TISSUGEL	PAIN	3/D 1/D	ORAL CUTANEOUS	12/24/2012	ONGOING
01-763	01-263	RDEYH38-FR	ZALDIAR DOLIPRANE 1000 CELEBREX	PAIN	2/D 3/D 2/D	ORAL	12/20/2012 12/20/2012 03/01/2013	ONGOING
01-764	01-264	RDEYH36-FR	DOLIPRANE 1000 CRESTOR 10 METFORMINE 850	PAIN HYPERCHOLESTEROLEMIA DIABETES	3/D 1/D 3/D	ORAL	12/12/2013 01/01/2006 01/01/1999	ONGOING
01-765	01-265	RDEYH38-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2013	ONGOING
01-766	01-266	RDEYH38-FR	IXPRIM METFORMINE 500	PAIN DIABETES	3/D	ORAL	03/01/2013 01/01/2005	ONGOING
01-767	01-267	RDEYH38-FR	IXPRIM MYOLASTAN	PAIN	3/D 2/D	ORAL	01/25/2013 03/01/2013	ONGOING
01-768	01-268	RDEYH36-FR	EFFERALGAN 1000	PAIN	3/D	ORAL	01/01/2013	ONGOING
01-769	01-269	RDEYH38-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2013	ONGOING
01-770	01-270	RDEYH36-FR	DAFALGAN CODEINE SEROPLEX 10 DEPAMIDE	PAIN DEPRESSION	3/D 1/D 3/D	ORAL	01/01/2013 01/01/2011 11/01/2011	ONGOING
01-790	01-290	RDEYH38-FR	DOLIPRANE 1000 METFORMINE 850 ZOCOR 20 TENORMINE 50	PAIN DIABETES HYPERCHOLESTEROLEMIA HYPERTENSION	4/D 2/D 1/D 1/D	ORAL	01/20/2013 01/01/2005 01/01/2005 01/01/2000	ONGOING
01-791	01-291	RDEYH38-FR	DOLIPRANE 1000 PREVISCAN TAHOR 10 ATACAND	PAIN ANTICOAGULANT HYPERCHOLESTEROLEMIA HYPERTENSION	1/D 0,75/D 1/D 1/D	ORAL	01/25/2013 02/25/2013 01/01/2004 01/01/2009	ONGOING
01-792	01-292	RDEYH38-FR	LAMALINE LEVOTHYROX LOPRIL	PAIN HYPOTHYROIDISM HYPERTENSION	3/D NK NK	ORAL	02/26/2013 01/01/2000 01/01/2000	ONGOING
01-793	01-293	RDEYH36-FR	LAMALINE	PAIN	1/D	ORAL	06/16/2012	ONGOING

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			Treatment	Indication	Posology	Administration route			
01-794	01-294	RDEYH36-FR	TRAMADOL	PAIN	1/D	ORAL	10/22/2012	ONGOING	
			EFFERALGAN 500		6/D		10/22/2012		
			METFORMINE 500	DIABETES	2/D		01/01/1998		
			ACEBUTOLOL	HYPERTENSION	1/D		01/01/1998		
HYPERTEN	1/D	01/01/1998							
01-795	01-295	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2013	ONGOING	
			SOTALEX	HYPERTENSION	1/D	ORAL	01/01/2000		
01-796	01-296	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2013	ONGOING	
			ENBREL		NK	ORAL	01/01/2010		
01-797	01-297	RDEYH36-FR	REVLIMID	MYELOMA	1/D	ORAL	02/01/2013	ONGOING	
			DAFALGAN CODEINE	PAIN	3/D		03/19/2013		
01-798	01-298	RDEYH36-FR	EFFERALGAN 1000	PAIN	3/D	ORAL	01/01/2010	ONGOING	
01-799	01-299	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	03/01/2013	ONGOING	
			IBUPROFENE		1/D		01/01/2011		
			APROVEL 300	HYPERTENSION	1/D				
01-820	01-320	RDEYH38-FR	LYRICA	PAIN	2/D	ORAL	02/13/2007	ONGOING	
			IXPRIM		4/D				
			RIVOTRIL		30/D				
			CYMBALTA		PAIN + DEPRESSION				1/D
			LAMALINE		PAIN				4/D
01-821	01-321	RDEYH38-FR	AVLOCARDYL	HEART	1/D	ORAL	12/11/2007	ONGOING	
			ASPEGIC 100	HEART	1/D				
			IXPRIM	PAIN	5/D				
			LYRICA 300	PAIN	1/D				
			TANGANIL	VERTIGO	3/D				
			IMOVANE	INSOMNIA	1/D				
			MENESTA 1	STRESS	1/D				
01-822	01-322	RDEYH38-FR	IXPRIM	PAIN	2/D	ORAL	01/03/2013	ONGOING	
			DOLIPRANE 1000		3/D				
01-823	01-323	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	03/01/2013	ONGOING	
			ASPEGIC 1000		3/D		03/01/2013		
			TENORETIC		HYPERTENSION		1/D		01/01/2011
			LAMALINE		PAIN		6/D		
01-824	01-324	RDEYH38-FR	IMOVANE	INSOMNIA	1/D	ORAL	07/28/2012	ONGOING	
			DEPOXAT	DEPRESSION					
			MYOLASTAN	MUSCLES CONTRACTION					
01-825	01-325	RDEYH38-FR	LAMALINE	PAIN	3/D	ORAL	03/05/2013	ONGOING	
01-826	01-326	RDEYH38-FR	LAMALINE	PAIN	6/D	ORAL	01/29/2013	ONGOING	
			BIPROFENID		1/D				
			DOLIPRANE 1000		3/D				
			EZETROL		HYPERCHOLESTEROLEMIA				1/D
01-827	01-327	RDEYH38-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	11/10/2012	ONGOING	
			MYOLASTAN		1/D				
			TOPALGIC		2/D				
01-828	01-328	RDEYH38-FR	IXPRIM	PAIN	6/D	ORAL	03/28/2013	ONGOING	
			AMOXICILLINE		4/D				
			FLAGYL		2/D				
			ZECLAR		2/D				
			MOPRAL		2/D				
01-829	01-329	RDEYH38-FR	LAMALINE	PAIN	6/D	ORAL	01/16/2013	ONGOING	
			TETRAZEPAM		1/D				
01-830	01-330	RDEYH38-FR	DOLIPRANE CODEINE	PAIN	3/D	ORAL	03/13/2013	ONGOING	
01-831	01-331	RDEYH36-FR	ACUPAN	PAIN	1/D	ORAL			
01-831	01-331	RDEYH36-FR	PARACETAMOL 1000	PAIN	3/D	ORAL	01/01/2013	ONGOING	
			PARACETAMOL 1000		3/D		01/01/2012		
01-832	01-332	RDEYH38-FR	IBUPROFENE 400	PAIN	2/D	ORAL	01/01/2013	ONGOING	
01-833	01-333	RDEYH36-FR	SOLUPRED	POLYARTHRITIS	1/D	ORAL	01/01/2008	ONGOING	
			OLMETEC	HYPERTENSION					
			DOLIPRANE 1000	PAIN					3/D
01-834	01-334	RDEYH36-FR	BIPRETERAX	HYPERTENSION	1/D	ORAL	01/01/2003	ONGOING	
			DOLIPRANE 1000	PAIN	3/D		01/01/2013		
01-835	01-335	RDEYH36-FR	EFFERALGAN 500	PAIN	6/D	ORAL	01/01/2000	ONGOING	
01-840	01-340	RDEYH38-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	03/28/2013	ONGOING	
			BIPRETERAX		HYPERTENSION		1/D		01/01/2005
01-841	01-341	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2013	ONGOING	
			BIPROFENID		1/D		01/01/2013		
01-842	01-342	RDEYH38-FR	LYRICA 50	PAIN	2/D	ORAL	12/18/2012	ONGOING	
01-843	01-343	RDEYH36-FR	DOLIPRANE 1000	PAIN	2/D	ORAL	01/01/2013	ONGOING	
			BIPROFENID		1/D		04/01/2013		

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			Treatment	Indication	Posology	Administration route	Date of beginning	
01-844	01-344	RDEYH36-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	03/22/2013	ONGOING
			TENORMINE 50	ANXIETY	1/D		03/22/2013	
			ELISOR 40	HYPERCHOLESTEROLEMIA	1/D		03/22/2013	
			KARDEGIC 75	ANTICOAGULANT	1/D		03/22/2013	
01-845	01-345	RDEYH36-FR	ACUPAN	PAIN	1/D	ORAL	04/01/2013	ONGOING
			LEVOTHYROX	HYPOTHYROIDISM	1/D		01/01/2010	
01-846	01-346	RDEYH38-FR	TOPALGIC	PAIN	2/D	ORAL	03/12/2013	ONGOING
			BIPROFENID	PAIN	2/D		03/12/2013	
01-847	01-347	RDEYH36-FR	VOLTARENE LP	PAIN	2/D	ORAL	04/08/2013	ONGOING
			DAFALGAN 1000	PAIN	3/D		04/08/2013	
01-849	01-349	RDEYH38-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/01/2013	ONGOING
			LEVOTHYROX	HYPOTHYROIDISM	1/D		01/01/1991	
01-850	01-350	RDEYH36-FR	LAMALINE	PAIN	3/D	ORAL	02/22/2013	ONGOING
			COAPROVEL	HYPERTENSION	1/D		01/01/2010	
01-851	01-351	RDEYH38-FR	PREVISCAN	ANTICOAGULANT	1/D	ORAL	03/02/2013	ONGOING
			LYRICA 25	PAIN	1/D		03/03/2013	
01-852	01-352	RDEYH38-FR	DOLIPRANE 1000	PAIN	3/D	ORAL	01/11/2013	ONGOING
			KARDEGIC 75	ANTICOAGULANT	1/D		01/11/2012	
01-853	01-353	RDEYH36-FR	NOLVADEX	BREAST CANCER	1/D	ORAL	02/08/2013	ONGOING
			DOLIPRANE 1000	PAIN	1/D		02/08/2012	
01-854	01-354	RDEYH38-FR	ADVIL 400	PAIN	4/D	ORAL	01/01/2011	ONGOING
01-855	01-355	RDEYH38-FR	DOLIPRANE 1000	PAIN	4/D	ORAL	03/01/2013	ONGOING
			TOPALGIC	PAIN	1/D		03/01/2013	
			NISIS 160	HYPERTENSION	1/D		01/01/2010	
			SKENAN 30	PAIN	1/D		04/01/2013	
01-856	01-356	RDEYH36-FR	IXPRIM	PAIN	4/D	ORAL	04/01/2013	ONGOING
04-702	04-102	RDEYH38-FR	DAFALGAN 1000	KNEE PAIN	3/D	ORAL	10/22/2012	ONGOING
04-703	04-103	RDEYH38-FR	NEURONTIN	PAIN	3/D	ORAL	01/01/2012	ONGOING
			TOPALGIC		3/D			
			MYOLASTAN		1/D			
			LAROXYL 50mg		1/D			
04-704	04-104	RDEYH36-FR	BIPROFENID	PAIN	2/D	ORAL	11/09/2012	ONGOING
			DAFALGAN 1000		3/D			
04-705	04-105	RDEYH38-FR	ACUPAN	PAIN	2/D	ORAL	09/22/2012	ONGOING
			LYRICA 150					
			VOLTARENE					
			MYOLASTAN					
04-706	04-106	RDEYH36-FR	ACUPAN	PAIN	3/D	ORAL	11/06/2012	ONGOING
			DAFALGAN 1000		2/D			
04-707	04-107	RDEYH36-FR	DAFALGAN 1000	PAIN	3/D	ORAL	05/01/2012	ONGOING
			HYPERIUM	HYPERTENSION	1/D		01/01/2005	
			LOXEN	HYPERTENSION				
04-708	04-108	RDEYH36-FR	LAMALINE	PAIN	3/D	ORAL	11/01/2012	ONGOING
			FORTZAAR	HYPERTENSION				
			PRAVASTATINE	HYPERCHOLESTEROLEMIA	1/D		01/01/2010	
			SEROPLEX	DEPRESSION			01/01/2012	
04-709	04-109	RDEYH38-FR	TOPALGIC	LUMBAR PAIN	1/D	ORAL	11/02/2012	ONGOING
			VOLTARENE		2/D			
04-710	04-110	RDEYH38-FR	DAFALGAN 1000	PAIN	3/D	ORAL	01/25/2012	ONGOING
			BIPROFENID		2/D		11/01/2012	
04-711	04-111	RDEYH36-FR	DAFALGAN 1000	LUMBAR PAIN	3/D	ORAL	11/14/2012	ONGOING
			TOPALGIC					

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16.2.4.4 Final patch location and time for pain improvement

Subject identification			Final location of the patches	Time to obtain pain relief (if inferior to 5 minutes)
Screening number	Randomisation #	Initials		
01-701	01-201	TJ	LEFT KNEE	NA
01-702	01-202	FP	RIGHT SHOULDER	NA
01-703	01-203	BA	RIGHT SHOULDER	NA
01-704	01-204	BS	RIGHT SHOULDER	NA
01-721	01-221	LC	LUMBAR	NA
01-722	01-222	CM	CERVICAL	NA
01-723	01-223	RM	LUMBAR	NA
01-724	01-224	MM	RIGHT SHOULDER	NA
01-725	01-225	TE	RIGHT SHOULDER	NA
01-726	01-226	CH	LEFT BUTTOCK	NA
01-727	01-227	SM	CERVICAL	NA
01-728	01-228	DP	RIGHT ANKLE	NA
01-729	01-229	BM	CERVICAL	NA
01-730	01-230	VM	LEFT BUTTOCK	NA
01-731	01-231	MG	RIGHT KNEE	NA
01-732	01-232	FJ	RIGHT HEMIFACE	NA
01-733	01-233	TT	LEFT KNEE	NA
01-734	01-234	VM	RIGHT MAMMARY ZONE	NA
01-735	01-235	GJ	RIGHT KNEE	NA
01-736	01-236	GL	RIGHT HIP	NA
01-737	01-237	CA	RIGHT KNEE	NA
01-738	01-238	GP	LEFT KNEE	NA
01-739	01-239	BN	LEFT KNEE	NA
01-740	01-240	BM	LUMBAR	NA
01-741	01-241	BZ	RIGHT SHOULDER	NA
01-742	01-242	PP	LUMBAR	NA
01-743	01-243	DM	LEFT ANKLE	NA
01-744	01-244	GY	LUMBAR	NA
01-745	01-245	GR	RIGHT KNEE	NA
01-746	01-246	GM	RIGHT ELBOW	NA
01-747	01-247	BC	CERVICAL	NA
01-748	01-248	RM	LEFT KNEE	NA
01-749	01-249	LA	RIGHT HIP	NA
01-750	01-250	FC	CERVICAL	NA
01-751	01-251	LE	RIGHT SHOULDER	NA
01-752	01-252	DV	BACKBONE	NA
01-753	01-253	PC	UNDER FEET	NA
01-760	01-260	FE	RIGHT KNEE	NA
01-761	01-261	VP	LEFT KNEE	NA
01-762	01-262	BA	RIGHT KNEE	NA
01-763	01-263	GB	LUMBAR	NA
01-764	01-264	MS	LUMBAR	NA
01-765	01-265	AM	CERVICAL	NA
01-766	01-266	RV	RIGHT KNEE	NA
01-767	01-267	BJ	RIGHT KNEE	NA
01-768	01-268	RE	RIGHT HAND	NA
01-769	01-269	GH	LUMBAR	NA
01-770	01-270	VF	RIGHT SHOULDER	NA
01-790	01-290	VJ	RIGHT KNEE	NA
01-791	01-291	CA	LEFT SHOULDER	NA
01-792	01-292	OR	LUMBAR	NA
01-793	01-293	MS	RIGHT KNEE	NA
01-794	01-294	RP	LEFT KNEE	NA
01-795	01-295	CM	CERVICAL	NA
01-796	01-296	VN	LEFT FOOT	NA
01-797	01-297	BC	LEFT RIBBING	NA
01-798	01-298	MJ	RIGHT SHOULDER	NA
01-799	01-299	CJ	CERVICAL	NA
01-820	01-320	CC	RIGHT HAND	NA
01-821	01-321	FS	RIGHT HIP	NA
01-822	01-322	TA	RIGHT SHOULDER	NA
01-823	01-323	NM	CERVICAL	NA
01-824	01-324	GF	LEFT HAND	NA
01-825	01-325	GM	RIGHT ANKLE	NA
01-826	01-326	VY	LEFT SHOULDER	NA
01-827	01-327	BB	LUMBAR	NA

Subject identification			Final location of the patches	Time to obtain pain relief (if inferior to 5 minutes)
Screening number	Randomisation #	Initials		
01-828	01-328	BA	RIGHT KNEE	NA
01-829	01-329	GS	RIGHT HAND	NA
01-830	01-330	LM	LEFT KNEE	NA
01-831	01-331	GY	DORSAL	NA
01-832	01-332	PG	RIGHT THUMB	NA
01-833	01-333	BS	LUMBAR	NA
01-834	01-334	TJ	LEFT SHOULDER	NA
01-835	01-335	JJ	LUMBAR	NA
01-840	01-340	MA	LUMBAR	NA
01-841	01-341	BV	CERVICAL	NA
01-842	01-342	TY	LEFT UPPER LIMB	NA
01-843	01-343	GJ	LUMBAR	NA
01-844	01-344	MD	LUMBAR	NA
01-845	01-345	GC	CERVICAL	NA
01-846	01-346	RC	RHIGHT KNEE	NA
01-847	01-347	DB	LUMBAR	NA
01-849	01-349	VP	CERVICAL	NA
01-850	01-350	GP	RIGHT KNEE	NA
01-851	01-351	TR	LEFT SHOULDER	NA
01-852	01-352	TG	LEFT SHOULDER	NA
01-853	01-353	YC	SHOULDER	NA
01-854	01-354	SJ	LUMBAR	NA
01-855	01-355	GG	LEFT HIP	NA
01-856	01-356	VC	LUMBAR	NA
04-702	04-102	ZS	RIGHT KNEE	NA
04-703	04-103	TD	UNDER FOOT	NA
04-704	04-104	BP	BUTTOCKS	NA
04-705	04-105	SK	RIGHT FEET	NA
04-706	04-106	SJ	LEFT HAND	NA
04-707	04-107	GJ	LEFT SHOULDER	NA
04-708	04-108	DB	UPPER DORSAL	NA
04-709	04-109	DM	LUMBAR	NA
04-710	04-110	BL	LEFT HIP	NA
04-711	04-111	NJ	LUMBAR	NA

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16.2.5 Data on treatment adherence or on drug concentration (if available)

Not applicable.

16.2.6 Individual Efficacy Response data

Pain scores on the EVA scale

Subject identification		Batch number	Pain score on T0 (mm)	Pain score on T5 minutes	Pain score on T15 minutes	Pain score on T1 hour
Randomisation #	Initials					
01-201	TJ	RDEYH38-FR	50	30	0	0
01-202	FP	RDEYH36-FR	100	100	80	70
01-203	BA	RDEYH36-FR	60	60	60	30
01-204	BS	RDEYH38-FR	60	60	60	60
01-221	LC	RDEYH36-FR	50	30	10	10
01-222	CM	RDEYH36-FR	60	60	40	20
01-223	RM	RDEYH36-FR	70	70	70	60
01-224	MM	RDEYH36-FR	50	20	20	10
01-225	TE	RDEYH38-FR	50	50	50	50
01-226	CH	RDEYH38-FR	60	60	50	30
01-227	SM	RDEYH38-FR	50	50	50	45
01-228	DP	RDEYH36-FR	50	50	30	20
01-229	BM	RDEYH36-FR	70	70	60	20
01-230	VM	RDEYH38-FR	60	60	60	0
01-231	MG	RDEYH36-FR	50	40	30	30
01-232	FJ	RDEYH36-FR	80	70	50	10
01-233	TT	RDEYH38-FR	60	60	60	60
01-234	VM	RDEYH36-FR	50	40	20	20
01-235	GJ	RDEYH36-FR	70	60	20	10
01-236	GL	RDEYH38-FR	50	35	30	20
01-237	CA	RDEYH38-FR	60	50	45	30
01-238	GP	RDEYH36-FR	60	60	40	20
01-239	BN	RDEYH38-FR	50	40	20	10
01-240	BM	RDEYH36-FR	60	30	10	10
01-241	BZ	RDEYH38-FR	90	60	50	50
01-242	PP	RDEYH36-FR	70	70	40	40
01-243	DM	RDEYH38-FR	50	10	10	0
01-244	GY	RDEYH38-FR	50	50	50	40
01-245	GR	RDEYH36-FR	50	50	30	10
01-246	GM	RDEYH36-FR	50	30	0	0
01-247	BC	RDEYH38-FR	50	50	50	50
01-248	RM	RDEYH38-FR	70	70	70	70
01-249	LA	RDEYH36-FR	70	70	30	0
01-250	FC	RDEYH36-FR	80	80	40	20
01-251	LE	RDEYH36-FR	70	60	50	0
01-252	DV	RDEYH38-FR	60	60	60	60
01-253	PC	RDEYH38-FR	50	50	50	50
01-260	FE	RDEYH36-FR	50	40	50	50
01-261	VP	RDEYH36-FR	50	30	20	0
01-262	BA	RDEYH38-FR	70	30	20	10
01-263	GB	RDEYH38-FR	70	50	40	50
01-264	MS	RDEYH36-FR	50	30	30	30
01-265	AM	RDEYH38-FR	80	80	80	80
01-266	RV	RDEYH38-FR	60	60	60	60
01-267	BJ	RDEYH38-FR	60	60	60	60
01-268	RE	RDEYH36-FR	70	70	50	20
01-269	GH	RDEYH38-FR	50	50	40	40
01-270	VF	RDEYH36-FR	70	70	40	40
01-290	VJ	RDEYH38-FR	50	40	40	35
01-291	CA	RDEYH38-FR	60	30	20	10
01-292	OR	RDEYH38-FR	80	70	70	70
01-293	MS	RDEYH36-FR	50	20	10	0
01-294	RP	RDEYH36-FR	50	40	40	10
01-295	CM	RDEYH36-FR	70	60	40	30
01-296	VN	RDEYH36-FR	50	50	20	20
01-297	BC	RDEYH36-FR	80	80	60	50
01-298	MJ	RDEYH36-FR	70	70	40	20
01-299	CJ	RDEYH36-FR	70	40	20	0
01-320	CC	RDEYH38-FR	80	80	80	80
01-321	FS	RDEYH38-FR	60	40	50	50
01-322	TA	RDEYH38-FR	80	70	70	70
01-323	NM	RDEYH36-FR	80	80	50	0
01-324	GF	RDEYH38-FR	90	90	100	100
01-325	GM	RDEYH38-FR	50	20	20	20
01-326	VY	RDEYH38-FR	50	40	60	50
01-327	BB	RDEYH38-FR	50	40	25	50

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Subject identification		Batch number	Pain score on T0 (mm)	Pain score on T5 minutes	Pain score on T15 minutes	Pain score on T1 hour
Randomisation #	Initials					
01-328	BA	RDEYH38-FR	70	40	60	70
01-329	GS	RDEYH38-FR	50	40	40	40
01-330	LM	RDEYH38-FR	50	40	40	60
01-331	GY	RDEYH36-FR	70	70	30	10
01-332	PG	RDEYH38-FR	50	50	50	50
01-333	BS	RDEYH36-FR	80	70	20	20
01-334	TJ	RDEYH36-FR	60	50	30	0
01-335	JJ	RDEYH36-FR	70	60	40	10
01-340	MA	RDEYH38-FR	80	80	80	90
01-341	BV	RDEYH36-FR	50	40	20	0
01-342	TY	RDEYH38-FR	50	50	50	50
01-343	GJ	RDEYH36-FR	50	40	25	10
01-344	MD	RDEYH36-FR	80	50	50	40
01-345	GC	RDEYH36-FR	60	60	40	20
01-346	RC	RDEYH38-FR	70	70	70	70
01-347	DB	RDEYH36-FR	100	70	50	15
01-349	VP	RDEYH38-FR	50	50	50	50
01-350	GP	RDEYH36-FR	50	50	50	50
01-351	TR	RDEYH38-FR	50	50	50	50
01-352	TG	RDEYH38-FR	70	70	70	70
01-353	YC	RDEYH36-FR	80	80	70	80
01-354	SJ	RDEYH38-FR	60	20	20	20
01-355	GG	RDEYH38-FR	50	50	50	50
01-356	VC	RDEYH36-FR	50	50	40	40
04-102	ZS	RDEYH38-FR	55	35	35	30
04-103	TD	RDEYH38-FR	50	40	20	20
04-104	BP	RDEYH36-FR	50	30	30	10
04-105	SK	RDEYH38-FR	50	30	30	50
04-106	SJ	RDEYH36-FR	70	20	40	40
04-107	GJ	RDEYH36-FR	90	60	50	40
04-108	DB	RDEYH36-FR	60	40	40	40
04-109	DM	RDEYH38-FR	50	30	30	20
04-110	BL	RDEYH38-FR	50	50	50	50
04-111	NJ	RDEYH36-FR	50	40	35	25

16.2.7 Adverse event listings (each subject) and concomitant treatments

16.2.7.1 Adverse event listing

No adverse event occurred during the study.

16.2.7.2 Concomitant treatments listing

No treatment was taken during the study.

16.2.8 Listing of individual laboratory measurements by subject, when required by regulatory authorities

Not applicable.

16.2.9 Case report forms

16.2.9.1 CRFs of deaths, other serious adverse events and withdrawals for AE

Not applicable

16.2.9.2 Other CRFs submitted

Not applicable.

16.3 Other Individual subject data listings (US Archival Listings)

Not applicable.