




STUDY TITLE: Single-site, Open-label Study Testing Horses for traces of Performance Enhancing Drugs (PEDs) post-AcuLife application

Principal Investigator: Kirk Shumpert, DVM, Principal Investigator

Study Site: S Bar S Ranch
884 County Road 1409, Mooreville, MS 38857.

Sponsored by LifeWave Inc. (San Diego, CA)

I have read this report and confirm to the best of my knowledge it accurately describes the conduct and results of the study.


Kirk Shumpert, Principal Investigator
S bar S Ranch

6/25/15
Date

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Abstract

This study's primary goal was to demonstrate that no performance enhancing drugs are being administered transdermally to horses by using Aculife patches. The hypothesis to be proven was "AcuLife patches do not introduce PEDs into the users body." The primary endpoint was blood sample analysis for traces of commonly known performance enhancing drugs (PEDs), as screened for by the American Quarter Horse Association. The secondary endpoint will be the horses health will not be adversely affected by the use of the multiple patches for a continuous period of time.

Principal Investigator, Kirk Shumpert, DVM, conducted the study and oversaw the horses at his horse ranch, located in Mississippi, USA, over the duration of the study.

The pilot study was open-label, single treatment with baseline samples compared to post-treatment after five days of continued use. Serum was sent to laboratory for the following testing:

- Thin Layer Chromatography (TLC)
- Enzyme Linked Immunosorbant Assay (ELISA)

As all results of the ELISA testing came back negative, the usual step of confirmatory testing was not necessary.

There is currently no requirement for drug testing in the Women's Professional Rodeo Association; however the association is currently considering implementing mandatory drug testing. Horses shown in the American Quarter Horse Association are subject to drug screens based on their performance at shows. Lifewave sponsored this study to further confirm to users that AcuLife patches do not introduce any drugs into horses. This will complement other studies that show the efficacy of the product in managing pain.

The lab contracted to analyze the samples for this study, *Center for Tox*, is also used by the American Racing Association, American Quarter Horse Association, Women's Professional Rodeo Association, and several other associations. An extensive list of drugs will be tested for before any patches are applied, then the animals will be re-screened after having worn the patches for five consecutive days.

Horses were screened beforehand to ensure no PEDs were in their system prior to beginning treatment and bloodwork confirmed horses showed no traces of PEDs after treatment, proving hypothesis as true. Horses were kept under surveillance by Principal Investigator for the duration of the study and no adverse effects were observed. LifeWave Inc, the manufacturer of the AcuLife patches sponsored this study.

Principal Investigator: Kirk Shumpert, DVM

Trial Design: Open label, single site

Objectives: To confirm manufacturer's claim that AcuLife does not introduce performance enhancing drugs, as defined by the American Quarter Horse Association, into a horse.

Background

This study will demonstrate that no performance enhancing drugs are being administered transdermally to horses by using Aculife patches.

There is currently no requirement for drug testing in the Women's Professional Rodeo Association; however the association is currently considering implementing mandatory drug testing. Horses shown in the American Quarter Horse Association are subject to drug screens based on their performance at shows. Lifewave is pro-actively seeking to prove that their patches do not introduce any drugs into horses. This will complement other studies that show the efficacy of the product in managing pain.

Study Design:

1) Screening

Horses will be drug tested as a qualifier for the study. After discussion with the laboratory, it was determined that the most comprehensive panel was the laboratory's pre-purchase panel. This panel is routinely run on horses by potential buyers to ensure the horse is not being given any drugs. This panel covers a wide range of substances commonly used in horses. Animals that qualify for this study will be tested to ensure their drug-free status before any patches are placed.

2) Testing

Enzyme Linked Immunosorbent assay or ELISA, is a rapid immunochemical test that involves an enzyme used for measuring a variety of body fluids. ELISA tests detect substances that have antigenic properties. Some of these substances include hormones, drugs, bacterial antigens, and antibodies. ELISA tests are generally highly sensitive and specific. When used for drug testing, a minimum concentration is usually set. ELISA tests are popular because they are fast and affordable as well as very accurate.

Thin layer chromatography or TLC, is a chromatography technique used to separate mixtures. TLC is performed on a sheet of glass, plastic, or aluminum foil, which is coated with a thin layer of adsorbent material like silica gel or cellulose. After the sample has been applied on the plate, a solvent is drawn up the plate via capillary action. Because different analytes ascend the TLC plate at different rates, separation is achieved. TLC can be used to monitor the progress of a reaction, identify compounds in a mixture and determine purity.

All eligible horses must be drug-free to be eligible for participation in this study and drug testing will be done as part of the screening. Animals will have blood samples taken: before patching (screening) and again after five days of patch placement.

Principal Investigator was requested to draw a minimum of 20ml per serum sample.

Samples were tested for: Albuterol, acepromazine, betamethasone, butorphanol, clenbuterol, detomidine, dexamethasone, flumethasone, flunixin, fluphenazine, isoxsuprine, lidocaine, mepivacaine, methyl prednisolone, pentazocine, promazine, reserpine, romifidine, acetylsalicylic acid, benzocaine, ephedrine, furosemide, ibuprofen, ketorolac, ketoprofen, meclufenamic acid, methyl phenidate, methocarbamol, naproxen oxyphenbutazone, phenylbutazone, phenylpropanolamine, procaine, and xylazine.

While the list of performance enhancing drugs tested for is in no way all inclusive, it is a very extensive list of drugs that are commonly given to horses to both directly boost performance and to mask lameness. The list is a stock list used by the Center for Tox Services in their pre-purchase blood panel.

3) Methods

Thin Layer Chromatography (TLC) and Enzyme Linked Immunosorbant Assay (ELISA) analysis was conducted on blood samples collected from the horses, after confirmation using the same testing, that no performance enhancing drugs (PEDs) were detected prior to intervention. Principal Investigator, a licensed veterinarian, conducted a physical exam two after the treatment ended to ensure horses were unharmed by treatment.

4) Physical Examination – was given prior to treatment and 24 hours after end of treatment.

- a. Capillary refill time
- b. Mucous membrane color
- c. Pupillary light response
- d. Auscultation of heart and lungs
- e. Heart rate
- f. Respiratory rate
- g. Body condition score
- h. Overall appearance

1. Exposure assignments

A single group, with all subjects being on the S bar S property for the duration of the study.

2. Study Schedule

Day 1: SCREENING/BASELINE: Horses will have blood sample drawn and sent to lab for analysis.

Days 5 – 10 [5 days starting when sample results return]: Open confirming drug-free status, samples results, five horses will be selected to wear five sets of patches for five consecutive days.

Day 11 [1 day after wearing patches]: A final veterinary physical exam will be conducted. This examination will cover major body systems and compare these values to pre patch exam values.

Participants:

5 horses, under Principal Investigator's care for the duration of the study at the S Bar S Ranch, located at 884 County Road 1409, Mooreville, MS 38857.

1. Inclusion criteria (Age, breed, and sex will be documented):
 - a. Free of Performance enhancing drugs prior to study; Healthy animals
2. Exclusion criteria:
 - a. Animals with detectable traces of PEDs;
 - b. Animals with chronic conditions that may require ongoing medical attention

Intervention: After screening, five sets of Aculife patches were applied to five acupuncture points selected for their use in a previous study using AcuLife on over forty horses for pain management.

Acupuncture points used were the following: Bladder 28, Bladder 23, Large Intestine 16, Bladder 13, and Bladder 10.

The LifeWave AcuLife patches are currently sold in the United States as a medical device for temporary pain relief and inflammation for horses. They are acupressure-based patches and work by placement on acupuncture points recommended by veterinarian and substantiated by research study data.

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 patches are a safe and effective new technology capable of gently stimulating acupuncture points without the use of needles. LifeWave's 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 nontransdermal, 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.

Results:

No trace of PEDs were shown in analysis of samples after five consecutive days of wearing five sets of acupressure patches as recommended by manufacturer.

Participant Demographic Data:

Name	Breed	Age	Sex
Macaroni	quarter horse	2	gelding
Monkey	paint	15	gelding
Ole paint	paint	5	mare
Rebel	pony	35	gelding
Smokey	quarter horse	16	gelding

Harms: No adverse events reported. Horses were given a complete physical examination conducted before the study and again the day after the study completed. In addition, the horses were checked daily when the patches were changed and also observed for any adverse signs twice daily at feeding time.

Conclusion: No performance enhancing drugs were present at the post treatment blood draw. This confirms the assertion that there are no performance-enhancing drugs (PEDs) in Aculife patches. In addition, the physical exam findings of the horses showed no adverse effects of the study or treatment.

Funding: This study was funded and test articles were supplied by LifeWave Inc. The protocol design was a result of collaborations of the Principal Investigator's expertise with equines and Lifewave's, as the manufacturer of the intervention, knowledge and experience with the use of AcuLife.

Instructions for Application of Treatment:

STEP 1

First, locate the acupressure point you wish to stimulate.

STEP 2

Next, remove a plastic bead from the bag.

Remove the adhesive backing of a WHITE patch. Place the plastic bead in the center of the adhesive side of the WHITE patch.

STEP 3

Place the WHITE patch with bead on the acupressure point you wish to stimulate, on the RIGHT side of the horse. Press down firmly on the patch to ensure it is secure.

STEP 4

Lastly, repeat steps 2-3 with a TAN patch, placing the TAN patch and bead on the same location, but now on the LEFT side of the horse.