



Title of research study:

The effects of CureWave laser on paraspinal muscle oxygenation, pressure pain thresholds, muscle edema, muscle quality, and perceived outcomes in patients with chronic low back pain.

Investigator:

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Key Information: The following is a short summary of this project to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are a male or female between the ages of 18 and 65 years old and have had the presence of low back pain for greater than 12 weeks. (5 episodes in your lifetime or 3 episodes in the last three years which altered activities of daily living). Exclusion criteria include:

- Self-reported pregnancy
- Inability to complete all required meeting sessions
- Known heart, lung, metabolic, or muscular conditions
- Regular use of prescription medication for your low back pain
- Seeking medical care for your low back pain
- Report average symptoms greater than 8/10
- Inability to perceive light touch over treatment site.

Why is this research being done?

Laser therapy utilizes light energy to help promote healing, similar feeling as placing a heating pad. Currently, there is little evidence to support the effectiveness of laser therapy for those with low back pain. Furthermore, it is unclear how individuals with low back pain will respond to laser therapy based on how chronic their symptoms are, how intense their low back pain is or where their pain is located. (e.g. is it only in the back or does it go into a leg). Therefore, our study seeks to evaluate how low back pain responds to high intensity laser therapy.

How long will the research last and what will I need to do?

We expect that you will participate in this research study for 4 weeks which will consist of two sessions per week of 30-60 minutes in length for a total of 8 visits. Also, a survey will be emailed to you at 3 months and another one at 6 months. Therefore, participation in the research project will last a total of 6 months with the two follow up surveys included. Participants will be asked to visit the UCF Institute of Exercise Physiology and Rehabilitation Science and participate in muscle function and sensitivity assessments as well as laser or placebo treatments (those in the placebo group will have the laser device held over their back but no laser energy will come out of the device).

Permission to Take Part in a Human Research Study

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More detailed information about the study procedures can be found under “*What happens if I say yes, I want to be in this research?*”

Is there any way being in this study could be bad for me?

Generally, the risks of participation are minimal and do not exceed the risk associated with activities found in normal daily life however some mild erythema (redness) and skin mottling (temporary blotchy red and purple skin) of the skin have been reported. There is also the potential for mild irritation from the gels and pads used for the different tests if participants have sensitive skin. Furthermore, the laser device produces a strong focus of light which may be harmful to the eyes however, participants will wear protective glasses to minimize any possible harm.

Will being in this study help me any way?

Some participants will be randomized into a group that will receive the laser treatment. Therefore, there may be some benefit in the form of a reduction in your lower back pain.

What happens if I do not want to be in this research?

Your participation in this study is voluntary. You are free to withdraw your consent and stop participation in this study at any time without penalty. Your decision to participate or not participate in this study will in no way affect your continued enrollment, grades, employment or your relationship with UCF or the individuals who may have an interest in this study. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team: at:

Dr. William Hanney p: 407.823.0217 e: William.j.hanney@ucf.edu

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at 407-823-2901 or irb@ucf.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect 36 people will be enrolled in this research study.

What happens if I say yes, I want to be in this research?

You will be asked to attend 8 visits that will each take 30-60 minutes. Each visit will be scheduled at least 24 hours apart; otherwise, the timing of each visit will be based on your convenience as long as you attend at least 2 times per week. On visits where the treatment will be given, (regardless of group assignment) each participant will wear protective glasses and be positioned in an area of the lab surrounded by a privacy curtain. Risk to participants is minimal; however, some reports of mild erythema (redness) of the skin has been reported with the application of laser therapy. Also, skin mottling (temporary blotchy red and purple skin) may occur.

Visits will consist of the following:

Visit #1 - You will report to the lab on the initial visit for inclusion and exclusion criteria screening. Also, you will be provided an opportunity to read over an informed consent form and ask any questions. Finally, baseline assessments will be run by a researcher. This visit will take about 60 minutes.

- Baseline assessments will include:
 - We will ask your age and biological sex as well as measure your height & weight
 - Muscle oxygenation (Near-infrared spectroscopy) – You will be asked to lie on your stomach. A researcher will lift the back of your shirt to clean the surface of your skin with an alcohol wipe and place a 3x4 inch patch on your back muscles. There will be no noticeable sensation other the feeling of pads on your skin. This test will measure muscle tissue oxygenation. You and the researcher will be located behind a privacy curtain during the test.



- Muscle echogenicity – You will be asked to lie on your stomach. The researcher will lift the back of your shirt and clean the surface with an alcohol wipe. A water-based ultrasound gel will then be applied over your back muscles. The researcher will use an ultrasound probe in the gel and move it over your back muscles. You will only feel a cool sensation from the ultrasound

gel. This assessment is to help us view your muscles and create digital ultrasound readings (pictures) to evaluate edema and muscle quality. You and the researcher will be located behind a privacy curtain during the test.



- Muscle pressure pain thresholds – You will be asked to lie on your stomach. The researcher will lift the back of your shirt and pressure will be placed over certain back muscles with a pressure sensor to evaluate tenderness. You will feel deep pressure in the different back muscles where the pressure sensor is applied. You will also be asked to let the researcher know when it feels mildly uncomfortable but should not feel painful. You and the researcher will be located behind a privacy curtain during the test.

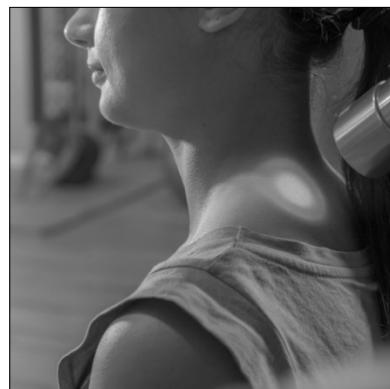


- EMG (electromyography). You will be asked to lie on your stomach. The researcher will lift the back of your shirt and your skin will be cleaned with alcohol wipes. Adhesive electrodes will be applied to your back muscles. Your feet will be stabilized with nylon straps and instruction will then be given to arch your back so we can evaluate your back strength. Muscle activity will be assessed using the wireless electrodes. You and the researcher will be located behind a privacy curtain during the test.



- Patient self-report questionnaires on pain, function and disability - You will be asked to complete a series of surveys to assess how you feel about your low back pain, how well you are able to get around, how active you are, and your sleeping patterns.

Visit #2 – You will undergo baseline assessments (as described above) and then be randomized into the study group or placebo group. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the researcher will choose what treatment you get. You will have an equal chance of being assigned to the experimental or placebo treatment. You will not be told which treatment you are getting; however, the researcher will know. Whether you are randomized into the laser group or placebo group you may or may not feel slight warmth (similar to a heating pad). Once you have completed the assigned treatment you will be asked to undergo baseline assessments again so we can evaluate the immediate effects of treatment. This visit will take about 60 minutes.



For the treatment you will be asked to lie on your stomach. The laser probe will be held over your lower back approximately 10 to 12 inches from your skin. In order to evaluate any possible adverse reactions, an initial treatment will be delivered at a lower intensity over two separate locations above the target treatment (see picture below). Upon conclusion of the initial test treatments (represented by blue dots), the skin will be evaluated for excessive redness or other changes in skin appearance. Also, you will be asked about any discomfort.

Should no unanticipated changes in skin appearance occur and you report no discomfort, the treatment will be administered. The process of applying the laser at decreased intensity will occur prior to each treatment. The laser probe which produces a red light will then be placed in 9 different positions over your low back for 1 minute in each position. It is thought that energy from the laser may help improve the healing potential of damaged tissue. You may or may not notice mild deep warmth. If you do feel a mild warmth this effect should only last for approximately 30 minutes.



- Laser treatment will be administered in 9 symmetrical positions which cover the lower back region. Dose will be 1 minute per position. During this time, it will feel similar to having a heat pad placed on your low back.
- Placebo treatment will consist of positioning the laser probe over the 9 symmetrical positions for 1 minutes each however no laser will be delivered.

Visits #3 - #8 – you will undergo a standardized treatment of the CureWave Laser or Placebo as described above. These visits will take 20-30 minutes.

Visit #8 – Upon conclusion of the 8th visit laser or placebo, you will complete the same assessments performed during the baseline assessments collected during visit #2. This visit will take about 60 minutes.

Email surveys – You will also receive an email with a link to an online survey 3 and 6 months after completion of the study. Each of the surveys will take approximately 20 minutes to complete.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to attend each of the 8 sessions and complete two follow up surveys.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. If you decide to leave the research, there are no adverse consequences. If you decide to leave the research, contact the researcher so they can make note of your departure in the files. If you stop being in the research, data already collected may not be removed from the study database.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, FDA and other representatives of this organization. However, the sponsor (CureWave Laser) will not have access to any identifiable information. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include adverse response to treatment including discomfort, excessive redness or mottling of skin (temporary blotchy, red-purplish marbling of the skin).

What else do I need to know?

This research is being funded by CureWave, Inc. CureWave Inc. is the manufacturer of the laser in this study and sells the laser. If you agree to take part in this research study, we will pay you \$100 for your time and effort. The payment will be made once you have completed the study; however, if you are unable to complete the study requirements you will be reimbursed based on the number of times you attended (about \$12 per session). Furthermore, you will receive an additional \$25 for completing the 3-month survey and another \$25 for completing the 6-month survey. The gift card will be given to you as soon as you complete each of the surveys. Reimbursement will be in the form of an e-gift card. Also, parking permits will be provided for all visits to the lab at no cost to the participant.

Participants are instructed to report any discomforts related to the study to the principal investigator. If immediate assistance is needed it will be provided via the emergency medical system. For non-emergency discomforts, participants must seek their own physician for medical attention. Adverse events/side effects will be reported to the IRB immediately upon notification. If a study subject suffers an adverse reaction, illness, or injury which, in the reasonable judgment of the institution, was directly caused by a Study Device or any properly performed procedures required by the protocol, the sponsor shall reimburse for the reasonable and necessary costs of diagnosis and treatment of any study subject injury, including hospitalization, but only to the extent such expenses are not attributable to (i) Institution's negligence or willful misconduct or (ii) the natural progression of an underlying or pre-existing condition or events, unless exacerbated by participating in the Study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent