Study of the Efficacy of 532nm Laser and 1064 nm Laser in the Treatment of Cutaneous Lupus Erythematous Versus Topical Corticosteroids Alone

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A Comparative Study of the Efficacy of 532nm Laser and 1064 nm laser as Adjuncts to Topical Corticosteroids in the Treatment of Cutaneous Lupus Erythematosus Versus Topical Corticosteroids Alone

Informed Consent

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Co-Investigators:	Naveed Sami M.D., Professor of Dermatology Amelia Winter, B.A., UCF College of Medicine Adam Foley, B.S., UCF College of Medicine Samantha Prabakaran, B.S., UCF College of Medicine Kyle Sommerfield, B.S., UCF College of Medicine
Sub-Investigators:	Sun Kim, B.A., UCF College of Medicine Rachel Diem-Trang Truong, B.A., UCF College of Medicine
Investigational Site(s):	UCF Health Clinic, 9975 Tavistock Lakes Blvd, Orlando, FL 32827, (407) 266-4900

Introduction: Researchers at the University of Central Florida (UCF) study many topics. To do this we need the help of people who agree to take part in a research study. You are being invited to take part in a research study which will include about 25 people in the Central Florida area. You have been asked to take part in this research study because you are older than 18, have at least 2 lesion of Cutaneous Lupus Erythematosus (CLE), and have the ability to rate your level of pain and visual satisfaction from the topical and laser therapy for the treatment of CLE. You must not have started or have a change in your medication for cutaneous lupus erytehamtosus, not be pregnant, and not allergic to the topical medication (triamcinolone or betamethasone dipropionate) to be included in the research study

The persons doing this research are Dr. David Weinstein and Dr. Naveed Sami of UCF Health, with the assistance of Samantha Prabakaran and Amelia Winter, medical students at the UCF College of Medicine.

What you should know about a research study:

- Someone will explain this research study to you.

- A research study is voluntary.
- Whether or not you take part is up to you.
- You should take part in this study only because you want to.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

New information developed during the course of the study which might affect the understandings in this consent and willingness to continue to participate will be brought to your attention.

Your participation in this study may be ended by the principal investigator or the sponsor if they feel it is in the interest of safety.

Purpose of the research study: Laser treatment is not currently an FDA-approved treatment of cutaneous lupus. The purpose of this study is to examine the effectiveness of two different types of laser in the treatment of CLE when used in addition to topical medications against the standard of care of topical medictions alone.

What you will be asked to do in the study:

- During this study you will have 2 or 3 of your CLE lesions selected to be included in the study. All of the lesions selected will be treated with topical medication (i.e. hydrocortisone cream). Of these 2 or 3 lesions, 1 or 2 will additionally receive laser therapy.
- Upon arrival at UCF Health, you will be given this consent form and the HIPAA Authorization form to read. You will be given the opportunity to ask any questions you may have. Afterwards you will asked to sign this document and the HIPAA Authorization before participation. You will be given instructions on how to care for skin before and after the laser treatments.
- This study will require three visits to the clinic over the span of 8 weeks.
    - First day of study (Visit 1):
        - During this first visit, you will be assessed by Dr. Weinstien to determine if you can participate in the study. He will then determine which of your CLE lesions will be included in the study.
        - Depending up on your skin type 1 or 2 of the lesions will receive treatment with a laser. Participants with lighter skin types will receive laser treatment to 2 different lesions, each treated with a different laser. Participants with darker skin types will only receive laser treatment to one lesion as one of the lasers is not safe for use on darker skin.
        - After treatment with the laser you will rate the amount of pain felt during the treatment. Dr. Weinstein will be completing all laser treatment.
    - 4 weeks later (Visit 2):
        - During this visit you will again be assessed by Dr. Weinstien.
        - You will be asked about to rate the appearance of your lesions.

        - The lesions treated before with the laser will again be laser treated a second time
        - After treatment with the laser you will rate the amount of pain felt during the treatment.
    - 4 weeks later (Visit 3):
        - This is the final visit and no laser treatment will take place.
        - During this visit you will again be assessed by Dr. Weinstien.
        - You will be asked about to rate the appearance of your lesions.
        - You will rate your final satisfaction in your visual appearance and answer some post-treatment questions
- For the duration of your time in the study you will be required to apply the topical medication provided to you twice a day to the study lesions.
- Photographs of the lesions being studied will be taken at each of the visits and stored in the electronic medical record.
- Your responsibility is to remain truthful about all inquiries about the treatment.

Location: The study will be conducted at UCF Health.

Time required: We expect that you will be in this research study for 30 minutes for each of the three visits over 8 weeks for a total of 1.5 hours over the course of the study.

Risks: There are no major anticipated risks associated with the study. Potential risks include:

Risk for laser treatment:

Risks: greater than 50% chance

- Pain/Discomfort – Additionally sharp burning/stinging pain can occasionally be felt.

Risks: less than 10% chance

- Redness/Swelling/Bruising – Short term redness (erythema) or swelling (edema) of the treated area is common and may occur. There also may be some bruising.
- Skin Color Changes – During the healing process, there is a possibility that the treated area may become either lighter (hypopigmentation) or darker (hyperpigmentation) in color compared to the surrounding skin. This is usually temporary, but, on a rare occasion, it may be permanent.
- Itching/Burning/Dry skin – Treatment may results in itching, burning, and/or dry skin during the recovery period.
- Red Rash/Bumps – Red rash/bumps may appear after treatment. This resolves with time.
- Acne flare-up or cold sore – this may occur after treatment.

Risks: less than 1% chance

- Wounds – Treatment can result in burning, blistering, scabbing, or bleeding of the treated areas.
- Infection – Infection is a possibility whenever the skin surface is disrupted, although proper self-wound care should prevent this.

- Scarring – Scarring is a rare occurrence, but it is a possibility when/if the skin surface is disrupted. To minimize the chances of scarring, it is important that you follow all post-treatment instructions provided by the research staff.

Other laser treatment risks:

- Sun Exposure / Tanning Beds / Artificial Tanning - May increase risk of side effects and adverse events mentioned above and must be avoided.
- Eye Exposure – Protective eyewear (shields or goggles) will be provided to you during the treatment. Failure to wear protective eyewear during the entire treatment may cause severe and permanent eye damage.
- Lack of improvement (procedure may not work) or worsening of your cutaneous lupus.

Risks for topical corticosteroid treatment:

- Thinning of skin
- Broken blood vessels
- Stretch marks
- Rash around the mouth
- Increase in hair in treatment areas
- Inflammation or irritation around hair follicles
- Note: All risks are approximately less than 5%

There may be uncommon or previously unforeseen risks. You should report any problems to the researcher.

Benefits: While there are no guarantees that you will receive any benefits from participating in this study, potential benefits include quicker improvement of your cutaneous lupus, less scarring than standard of care, and topical treatment at no cost for cutaneous lupus for duration of study participation.

Alternatives: The alternative to choose to not participate in the study.

Compensation or payment: You will not be receiving any compensation for your participation in the study.

Cost: There will be no cost to you or your insurance company to participate in this study. Please read about other possible costs in the following page under If you are harmed because you take part in this study.

Confidentiality: We will limit your personal data collected in this study to people who have a need to review this information. We cannot promise complete secrecy. You may possibly be recognizable from some of the photographs taken of the lesions. Organizations that may inspect and copy your information include the IRB and other representatives of UCF. There is the possibility that the Food and Drug Administration (FDA) and/or the Office for Human Research Protections (OHRP) may inspect the research records.

Monitors, auditors, IRB, and regulatory authorities will be granted direct access to all participants' original medical records for verification of clinical trial procedures and data, without violating your confidentiality, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the you or your legally authorized representative is authorizing such access.

If the results of the trial are published, your identity will remain confidential.

Study contact for questions about the study or to report a problem: If you have questions, concerns, or complaints, or think the research has hurt you, talk to Dr. David Weinstein MD, UCF College of Medicine, UCF Health at david.weinstein@ucf.edu or Samantha Prabakaran, Medical Student, UCF College of Medicine at sprabakaran@knights.ucf.edu.

IRB contact about your rights in the study or to report a complaint: Research at the University of Central Florida involving human participants is carried out under the oversight of the Institutional Review Board (UCF IRB). This research has been reviewed and approved by the IRB. For information about the rights of people who take part in research, please contact: Institutional Review Board, University of Central Florida, Office of Research & Commercialization, 12201 Research Parkway, Suite 501, Orlando, FL 32826-3246 or by telephone at (407) 823-2901. You may also talk to them for any of the following:

- 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 want to get information or provide input about this research.

If you are harmed because you take part in this study: If you are injured or made sick from taking part in this research study, medical care will be provided. Depending on the circumstances, this care may be provided at no cost to you. Treatment for research related minor injuries will be made available at no cost by Dr. Weinstein if possible. For injuries that cannot be treated by Dr. Weinstein you will be referred elsewhere. Costs associated with this treatment may be billed to your insurance company. Costs not covered by your insurance company will be your responsibility. Contact the investigator for more information.

Withdrawing from the study: You can withdraw from the study at any time during the study by contacting the principal investigator or co-investigators. If you decide to leave the research, data will no longer be collected from you and you are free to leave, however data collected up to that point will be used. There will be no consequences for your choice to leave. If you decide to leave the study, contact the investigator so that the investigator can stop recording data from you. The principal investigator can also remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions from staff or adverse reaction to one of the local anesthetic solutions. The principal investigator can also end the research study early. We will tell you about any new information that may affect your health, welfare or choice to stay in the research. Withdrawal from this study will not affect your healthcare.

University of Central Florida IRB
IRB Number: MODCR00000134
IRB Approval Date: 5/22/2019
IRB Expiration Date: 5/21/2020

Your signature below indicates your permission to take part in this research and to the use and disclosure of your protected health information.

DO NOT SIGN THIS FORM AFTER THE IRB EXPIRATION DATE BELOW

Name of participant	Phone Number
Signature of participant	Date
Signature of person obtaining consent	Date

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