The Effects of Fractional CO2 Laser on Poikiloderma of Civatte

Informed Consent Form

NCT04581330

Approval Date: 10/09/2020

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center

Key Information about this Study

The aim of the study is to assess the safety and efficacy of fractional CO2 laser for treatment of Poikiloderma of Civatte (POC). The study subjects' neck and décolletage area will be divided into two equal halves. The line of division will be from the mid mental protuberance to manubriosternal junction. One half of the neck and upper chest area will be treated with ablative fractional CO2 laser while the other half will be untreated and used as a control. If desired after the study endpoint, patients may have the other side of their neck treated at no additional charge.

The duration of the study is 24 weeks, including 3 in person clinic visits: initial procedural visit, 12-week follow up then 24-week follow up.

There are risks to this study device that are described in this document. Some risks include: ocular injury, pain, infection, post inflammatory pigmentary changes, prolonged erythema, scarring.

Potential benefits of the study:
- Improved overall dyschromia and telangiectasia of the chest and neck area
- Overall increased patient satisfaction and quality of life
- Provide patients safe and effective alternative for treatment of discoloration and atrophy of neck and chest area which hopefully can be generalized to similar patient populations.

If you are interested in learning more about this study, please continue to read below.

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Heather Goff, MD, MPH Department of Dermatology at UT Southwestern Medical Center in Dallas TX.

There is no conflict of interest with any research team members.

Funding
There will also be no costs to the patients for the laser procedures as funding will be supplied by the UT Southwestern Dermatology department via an educational grant. Patients desiring treatment of the control side after the study end-point (24 weeks) will be provided at no cost for the participants.

Purpose – "Why is this study being done?"

You are asked to participate in this research study to assess the safety and efficacy of fractional CO2 laser for treatment of Poikiloderma of Civatte (POC). This study will help find out what effects, good and/or bad, fractionated CO2 laser has on POC. The safety of has in humans has been tested in prior research studies; however, some side effects may not yet be known.

This study involves the use of an investigational device called fractionated CO2 laser. "Investigational" means that the fractionated CO2 laser devie has/have not yet been approved by the U.S. Food & Drug Administration (FDA) for treating poikiloderma of civette.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you have clinically evident poikiloderma of civatte that can potentially benefit from fractionated CO2 laser treatment. Additionally you meet all the inclusion and exclusion criteria for the study.

How many people are expected to take part in this study?
This study will enroll approximately 15 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 3 visits with the researchers or study staff.

The initial visit will take approximately 2 hours (mainly time of topical anesthesia and procedure time). The subsequent 2 visits should take 30 min each (mainly filling out surveys and taking high resolution photos) .

The results of the procedure will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you.

No blinding involved in the study.

Study Procedures - as a participant, you will undergo the following procedures:
Patients with a clinical diagnosis of POC defined by a skin change with atrophy, hypopigmentation, hyperpigmentation, dilation of the fine blood vessels (telangiectasia) will be recruited. Ten patients will be consented. Before the initial visit, all patients will complete a one-month preoperative daily use of SPF 50+ sunscreen. The sun protection is to reduce further sun damage and protect skin from increased photosensitivity that may occur after laser resurfacing. At the initial visit, high resolution photographs of the affected area on the neck and décolletage area will be taken. All patients will fill out a form with demographic information. Patients will be instructed to come to their appointment with clean skin and without any lotions or moisturizers on the neck or décolletage area. Laser-specific eyewear will be provided to practitioners, patients, and all other people in the treatment room. A blue skin marking pen will be used to draw a line from mid mental protuberance to manubriosternal junction to divide tested area into

two equal halves. Compounded benzocaine, lidocaine, and tetracaine (BLT) cream in a 20:8:4% concentration will be applied to the treatment area for 40 minutes prior to the procedure. Before the treatment, topical anesthesia will be thoroughly washed off with chlorhexidine gluconate and distilled water. One pass with a 1-mm spot density and a 60micron depth will be performed followed by a 1mm spot density and a 200-micron depth will be used. The other half of the testing area will be left intact and used as the control for easy comparison. The side that undergoes treatment will be selected randomly. Forced cold air (Zimmer cooler) will also be used in conjunction with the laser device for better patient comfort.
Cold compresses with refrigerated distilled water can be used to reduce swelling and to soothe the skin with frequent reapplication of white petrolatum to keep the skin coated for days 1-5 post-procedure with strict sun avoidance for the first week post-procedure. Daily use of broad-spectrum sunscreen with SPF50+ will be required after the first week.

Given the current pandemic, limited in-person follow-ups will be scheduled (once at baseline before treatment, then at 12 and 24-weeks post-treatment. Assessment surveys will be filled out and high-resolution photo of the head and upper chest area will be taken at each in person follow ups. Participants will communicate immediate post-treatment issues or concerns along with selfies through MyChart on day 2, 3, 7, 10, 14 to track progress and to identify any post procedural complications in a timely fashion. Participants will be given options for in-person office visits or tele-health virtual clinic visits if concerns arise after the procedure.

There will also be no costs to the patients for the laser procedures as funding will be supplied by the UT Southwestern Dermatology department via an educational grant. Patients desiring treatment of the control side after the study end-point (24 weeks) will be provided at no cost for the participants.

Potential Risks:

- Ocular – severe ocular complications such as corneal ulceration and cataract could happen with any laser devices. Therefore, CO2 laser specific eyewear will be provided to everyone in the treatment room. Ocular complication for this study should be low since we are mainly targeting the neck and upper chest area instead of the facial area.
- Pain – Topical anesthesia, and a forced-air cooling device will be used to help patients tolerate the procedure. Prolonged severe pain postoperatively may indicate other complications such as infection infection and patient should contact the investigators and will be examined in-person to determine the cause.
- Infection – patients will be counseled on signs of infection such as increased erythema, purulence, oozing and crusting. Patients will submit electronic selfies of the treatment area electronically to investigators on day 2, 3, 5, 7 and 10. Investigators will contact patients if any signs of infection are identified. For patients with skin infection within the past 6 months, topical mupirocin ointment TID applied to the nares will be prescribed to prevent staph colonization.
- Post-inflammatory hyperpigmentation: This usually happen less frequently in lighter skin types which are the groups most commonly affected by POC. However, should this occur, hydroquinone and topical retinoids can be prescribed for the patient at the study end-point to alleviate the dyschromia.
- Prolonged erythema: if erythema lasts more than 3 weeks postoperatively, a mid-potency topical steroid will be prescribed to the patient.
- Scarring: patients with personal and family history of keloid disease and hypertrophic scar formation will be excluded from the study. If hypertrophic or keloidal scars happen, intralesional steroids will be used to flatten the scars.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.

- You do not follow instructions from the researchers.
- The study is stopped.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician.

Risks – "What are the risks of participation in the research?"

Potential Risks:

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• Scarring: patients with personal and family history of keloid disease and hypertrophic scar formation will be excluded from the study. If hypertrophic or keloidal scars happen, intralesional steroids will be used to flatten the scars.

Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

The following section will describe the risks related to each your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

For more information about risks and side effects, ask one of the researchers or study staff.

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete a final study visit. This visit includes discussion of the reasons for discontinuation of the study, possible adverse events related to the procedure, taking final high-resolution photos of the neck and chest area. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?

Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"
The possible benefit of your participating in this study includes:
- Improved overall dyschromia and telangiectasia of the chest and neck area
- Overall increased patient satisfaction and quality of life
- Provide patients safe and effective alternative for treatment of discoloration and atrophy of neck and chest area which hopefully can be generalized to similar patient populations.

There is no guarantee or promise that you will receive any benefit from this study.

We hope the information learned from this study will benefit other people with similar conditions in the future.

Payments – Will there be any payments for participation?
There will be no monetary payments for participating in this study.

Costs – Will taking part in this study cost anything?

The sponsor will provide the procedure free of charge during this study.

Confidentiality – How will your records be kept confidential?
Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Your personal information and/or biospecimens collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and

the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

Your medical history and blood work, information that we get from your medical record, information contained in your underlying medical records related to your medical history and treatments prior to the study, information that is created or collected during your participation in the study including medical and treatment history, information you give us during your participation in the study such as during interviews or from questionnaires; demographic information like your age, marital status, the type of work you do and the years of education you have completed.

We will get this information by asking/surveying you, asking your doctor, by looking at your chart in the UTSW EPIC system.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the Sponsor, UTSW Department of dermatology, funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- the members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the University of Texas Southwestern Medical Center for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.
After you enroll in this study, you may ask the researchers to stop using your health information at any time . However, you need to say this in writing and send your letter to Heather Goff, MD, MPH, 5939 Harry Hines Blvd 4th floor suite 100, Dallas, TX 75390. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Yi Yang, MD can be reached at 832-588-8336 or email address: Yi1.Yang@utsw.edu

If primary is not available, contact
Research assistant, Agnes Kim can be reached at 206-883-6503 or email address: agnes.kim@utsouthwestern.edu

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Signature Section

			AM PM
Printed Name of Participant	Signature of Participant	Date	Time
			AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

Witness / Interpreter Signature Section

Interpreter/witness (Interpreter signature required per hospital policies when physically present.)

I attest that I have interpreted the information in this consent form and it was explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

			AM PM
Printed Name of Interpreter	Signature of Interpreter	Date	Time

Witness Signature (required when interpreter is not physically present-e.g., Language Line is used):

By signing below:

I attest that the information in the consent form was accurately explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of witness	Signature of witness	Date	Time AM PM

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:
By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM