A single center, double-blinded randomized placebo-controlled trial to evaluate surgical scars after treatment with fractional carbon dioxide rejuvenation laser therapy

NCT02985151

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SAINT LOUIS UNIVERSITY

Research Study Consent Form

STUDY TITLE:	A single center, double-blinded, randomized placebo-controlled trial to evaluate surgical scars after treatment with fractional carbon dioxide rejuvenation laser therapy.

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

RESEARCH STUDY CONSENT FORM

Participant:		**IRB #:**	27403
	First Name / Last Name		
Principal Investigator (PI)	Ramona Behshad, M.D.	**Contact Phone #**	314-977-9721
	First Name / Last Name Credentials		
Title of Project:	A single center, double-blinded, randomized placebo-controlled trial to evaluate surgical scars after treatment with fractional carbon dioxide rejuvenation laser therapy.		

"You" refers to the person who takes part in the research study.

You are being asked to take part in a research study conducted by Dr. Ramona Behshad and colleagues because you have a surgical scar on your head and neck that has never been treated with a cosmetic laser.

This consent document may contain words that you do not understand. Please ask the research study doctor or research staff to explain anything that you do not understand.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

This study seeks to determine how well an FDA approved laser, the Syneron-Candela CO_2RE laser, can improve surgical scars on the face and neck. Lasers are devices that deliver an intense wavelength of light and have been used by physicians for many years. Surgical uses for lasers range from cutting, destroying, or selectively removing layers of skin and fat. The carbon dioxide laser being used for this study has FDA approval to treat many skin conditions including surgical scars. The information from this study will help doctors know if this laser is the ideal treatment for unwanted scars that result from various types of surgery, such as Mohs surgery (a surgery to remove certain types of skin cancer). No more than 50 subjects will be enrolled at Saint Louis University.

2. WHAT AM I BEING ASKED TO DO?

Research participants will be assigned by chance (50/50) to receive either a high energy laser treatment or a low energy laser treatment. This process is called randomization. A low energy laser treatment will look similar to the study treatment, but has less penetration in the skin, and will likely be less effective. Other than the investigating physician performing the laser treatment, no one (including you and the physicians who will be evaluating the response to treatment) will know who is receiving the high energy treatment or the low energy treatment. This way the results of the research study will not be favored one way or another. If it becomes necessary for your care, the investigator will be able to tell you whether you are receiving the high energy laser treatment or low energy laser treatment.

There will be between three and five study office visits:

- a screening visit to determine if you are eligible and appropriate for the study
- first treatment visit (this may take place at the same time as the screening visit, or within 30 days)
- second treatment visit 3 months after the first treatment
- Follow up visit 3 months after the second treatment; at this visit you will be told if you received the high energy laser treatment or the low energy laser treatment and will be given options:
    - If you received high energy laser treatment you may elect a third treatment
    - If you received a low energy laser treatment you may elect to receive a high energy laser treatment at this visit and again in 3 months
    - If you do not desire any additional treatment you may exit the study at this visit
- If you elected to receive additional 1 or 2 treatments, you will be asked to return 3 months after your final treatment for a follow up visit and study exit

Screening Visit (1 Hour to 1.5 Hours)

You will verify information regarding your name and contact information. You cannot take part in this study if you have a history of prior laser treatment to the face or neck, or if you tend to form keloid scars or scars from minor trauma. Also you should not participate in the study if you have taken oral isotretinoin medication within the past 6 months. In addition, the principle investigator may exclude you from the study if she determines that the study may put you at risk. You will provide your written consent (permission) to be a participant in the study and for the research team to access your health information to learn more about the surgery that resulted in the scar and the original features of the scar. Immediately before any study visit, you will be asked to not wear any make-up or use facial moisturizers (or moisturizers on the neck). You will be asked to cleanse your face with a gentle cleanser, such as Cetaphil, provided in the office prior to treatment.

Other procedures at this visit:

- You will have photographs taken of the scar that will be shared confidentially with two other research physicians in the study for them to answer questions about the scar.
- You will complete a questionnaire about the scar and another research physician will see you at this visit to evaluate the scar.

If you qualify for study treatment the following may occur at the same visit or at a return visit within 30 days. The following will occur:

- If you have a history of recurrent fever blisters/cold sores on the lips or face, you will be offered a three day prescription for an antiviral medication that you can fill at your pharmacy to prevent a recurrence since laser treatments may increase the chance of recurrent episodes. You would take one pill every twelve hours the day prior to treatment, on the treatment day, and the first day post-treatment. You or your insurance plan must cover the cost of the medication. This may delay the treatment to a later date within 30 days of the screening visit.
- You will complete a pre-treatment questionnaire
- You will receive laser treatment as randomized to either high energy or low energy treatment which includes:

- Prior to treatment, you will be asked to cleanse your face with a gentle cleanser, such as Cetaphil, provided in the office in order to remove all lotion, creams, make up, and sunscreen.
- A topical anesthetic medication will be applied to the treatment area approximately 20 minutes prior to the procedure. If the scar is deeper, an injection of numbing medicine may be used as well. Once this time passes and the numbing medicine is working, you will be escorted to the procedure room. The treatment areas will be wiped clean of the numbing cream prior to the procedure.
- Just prior to the procedure, your eyes will be covered with eye shields to protect your eyes.
- The treatment time may vary, but generally takes 10 minutes or less. During this time, you will hear the laser, which sounds like a bee buzzing, and will feel some warmth. Most report minimal discomfort during the procedure. There may be pinpoint bleeding, bruising, and crusting depending upon the area and extent of the treatment. . After the treatment, you will be provided with a diary to daily record treatment-related reactions: redness, swelling, pain, itching or color changes following treatment.
- You will be given post-treatment instructions
- You will be given a paper diary to record possible reactions such as redness, swelling, pain, itching or color changes following treatment

Study Visit 2 (30-45 min)

You will be asked to return in 3 months for a second treatment visit with the following activities:

- You will complete a pre-treatment questionnaire
- You will receive laser treatment as randomized to high energy or low energy treatment
- You will obtain post-treatment instructions
- You will obtain a paper diary to record possible reactions such as redness, swelling, pain, itching or color changes following treatment
- If you have a history of recurrent fever blisters/cold sores on the lips or face, you will be offered a three day prescription for an antiviral medication that you can fill at your pharmacy to prevent a recurrence since laser treatments may increase the chance of recurrent episodes. You would take one pill every twelve hours the day prior to treatment, on the treatment day, and the first day post-treatment. You or your insurance plan must cover the cost of the medication. This may delay the treatment to a later date within 30 days of the screening visit.

Study Visit #3 (45 min up to 1.5 Hours)

This visit occurs 3 months after your second treatment with the following activities:

- You will return your diary
- You will complete a questionnaire
- You will undergo scar evaluation by the research physician
- You will have photographs taken
- The treating investigator will let you know which treatment you received

If you received the high energy laser treatment, the following will occur:

- You will be offered the option to receive a third high energy treatment.
- If you accept treatment today, you will return in 3 months for a follow up final study visit (Visit 4).
- If you decline further treatment, you will be exited from the study.

If you received the low energy laser treatment, the following will occur:

- You will be offered the option to receive two high energy treatments.
- If you accept treatment you will receive one treatment today and return in 3 months for the second treatment (Visit 4); you will then be asked to return 3 months later for a follow up final study visit (Visit 5).
- If you decline further treatment, you will be exited from the study.

If you elect to receive treatment, the following will occur:

- you will obtain post-treatment instructions
- You will obtain a paper diary to record possible reactions such as redness, swelling, pain, itching or color changes following treatment
- If you have a history of recurrent fever blisters/cold sores on the lips or face, you will be offered a three day prescription for an antiviral medication that you can fill at your pharmacy to prevent a recurrence since laser treatments may increase the chance of recurrent episodes. You would take one pill every twelve hours the day prior to treatment, on the treatment day, and the first day post-treatment. You or your insurance plan must cover the cost of the medication. This may delay the treatment to a later date within 30 days of the screening visit.

Study Visit 4 (30-45 min.)

If you were originally treated with the high energy laser, and elected a third treatment at Visit 3, this visit occurs 3 months after your Visit 3 treatment with the following activities:

- You will return your diary
- You will complete a questionnaire
- You will undergo scar evaluation by the research physician
- You will have photographs taken
- You will be exited from the study

If you were originally treated with the low energy laser, and elected treatment with the high energy laser, this visit occurs 3 months after your Visit 3 treatment with the following activities:

- You will complete a pre-treatment questionnaire
- You will receive the last high energy laser treatment You will obtain post-treatment instructions
- You will obtain a paper diary to record possible reactions such as redness, swelling, pain, itching or color changes following treatment
- If you have a history of recurrent fever blisters/cold sores on the lips or face, you will be offered a three day prescription for an antiviral medication that you can fill at your pharmacy to prevent a recurrence since laser treatments may increase the chance of recurrent episodes. You would take one pill every twelve hours the day prior to treatment, on the treatment day, and the first day post-treatment. You or your insurance

plan must cover the cost of the medication. This may delay the treatment to a later date within 30 days of the screening visit.
- You will asked to return in 3 months for a final follow- up visit

Study Visit #5 (45 min)
This visit occurs 3 months after your last treatment if you received the low energy laser treatment followed by the high level laser therapy as a final study visit. You will not be offered treatment at this follow up visit. The following will occur:
- You will return your diary
- You will complete a questionnaire
- You will undergo scar evaluation by the research physician
- You will have photographs taken.

At any time, you may choose to not participate in the study. However, if you chose to withdraw from the study before the termination of the study, you will still receive a phone call from the study team one week later to -to check on if you are experiencing any new, unwanted effects from the prior study treatment and will be provided with guidance for that situation.

3. HOW LONG WILL I BE IN THE RESEARCH STUDY?

The time you may spend on this research study is up to 14 months. Study visits will be every three months.

The research study should be completed by July 2018.

4. WHAT ARE THE RISKS?

There are certain risks and discomforts that may occur if you take part in this research study. Risks relate to both the use of laser energy and to other study procedures performed. Although the majority of patients do not experience these complications, you should discuss each of them with your physician to make sure you understand the risks, potential complications, and consequences of laser skin treatment.

- Crusting (scaly thickened skin)-Very common side effect after laser treatment, severity varies between individuals, resolves over days

- Swelling-Common side effect after laser treatment, severity varies between individuals, self-resolves days to weeks

  Burning sensation-Common side effect after laser treatment, severity is mild to moderate, self-resolves hours-to-days, with avoidance of harsh alcohol-based personal hygiene products
- Dry skin at treatment site-Common side effect after laser treatment that reverses with a skin moisturizer cream

- Itching at treatment site- Common side effect after laser treatment, severity varies, relieved with a skin moisturizer

- Eye damage- Uncommon side effect, severity varies, eye protection worn during the treatment as provided by our office minimizes damage to your eyes

- **Infection-Although infection following laser treatment is unusual, bacterial, fungal, and viral infections may occur. Herpes simplex virus (HSV) infection around the mouth or other areas of the face can occur following a laser treatment causing cold sores/fever blisters. This applies to both individuals with and without a past history of HSV fever blisters in the mouth area. Specific medications may be prescribed and taken prior to and following laser treatment procedure in order to suppress an outbreak of a fever blister. Should any type of skin infection occur, additional treatments including antibiotics may be necessary, with prescriptions to your pharmacy that must be paid for by you or your insurance. Side effects of the antiviral medication that treats fever blisters are uncommon and may include: nausea, vomiting, diarrhea, headache, weakness, lightheadedness, rash, swelling of the lips and/or eyes, joint pain, confusion, agitation, light-sensitivity induced rashes, and potential kidney damage; more severe but less common effects include hallucinations, altered ways of thinking or behaving, seizures, coma, as well as blood disorders such as low red cell or white cell counts, the potential for allergic reactions, and breathing difficulty.**

- **Bleeding-On rare occasions there may be some minor bleeding at the site receiving laser treatment. This will stop shortly after the treatment with application of a tight bandage.**

- **Scarring-Although normal healing after a procedure is expected, abnormal scars may occur both in the skin and deeper tissues. In rare cases, keloid scars may result. Scars may be unwanted or a different color than the surrounding skin. Additional treatments such as corticosteroid injections may be needed to treat scarring.**

- **Burns-Laser energy may produce burns. Nearby skin and surrounding structures, including the eyes, may be injured or permanently damaged by the laser beam. Burns are rare as an effect of the heat produced within the tissues by laser energy. Additional treatment such as topical ointments and prescribed oral antibiotics may be necessary to treat laser burns.**

- **Color change-Laser treatments may potentially change the natural color of your skin. Skin redness usually lasts 2 weeks-3 months and occasionally 6 months following laser skin treatment. There is a possibility that treated skin may contain areas that are either lighter or darker than your skin. A visible line separating normal skin and skin treated with lasers can occur.**

- **Laser smoke (plume)-Laser smoke may represent a possible hazard to your health. A smoke evacuator (a device that removes smoke fumes) attached to the laser will be utilized to minimize your exposure.**

- **Isotretinoin-isotretinoin is a prescription medication used to treat certain diseases such as severe acne. This drug may impair the ability of skin to heal following treatments or surgery for variable amount of time even after the patient has stopped taking it. Individuals who have taken the drug are advised to allow their skin time to recover before undergoing laser skin treatment procedures. If you took isotretinoin in the last six months, you should not participate in this study.**

- **Damaged Skin-Skin that has been previously treated with chemical peels or dermabrasion (a procedure to remove the top layers of your skin) or damaged by burns, electrolysis (hair removal treatments), or radiation therapy may heal abnormally or slowly following treatment by lasers or other surgical techniques. If you have previously damaged skin in the treatment area, you may still participate in the study, but may have an increased risk of slow or abnormal healing following the laser treatment.**

- **Distortion of Anatomic Features-Laser skin treatments can produce swelling of the eyelids, mouth, and other facial areas. Should this occur, ice or elevation of the treatment area can be done.**

- **Pain-Very infrequently short term pain (such as a burning or stinging sensation) may occur after laser skin treatment procedures**

- **Allergic reactions-In rare cases, local allergies to tape, topical ointments have been reported. Reactions, affecting all of your organs, which are serious may result from drugs used during medical procedures and prescription medicines. Allergic reactions may require additional treatment.**

- **Delayed Healing-It may take longer than anticipated for healing to occur after laser treatments. Skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after a laser treatment.**

- **Topical and/or local anesthesia- Topical and/or local medication used to numb the treatment area prior to the laser treatment may be offered. Allergic reactions to anesthetic (numbing) agents such as lidocaine, in the doses to be used in this study, are rare and may include skin rash, redness, itching, hives, burning, stinging, swelling, tenderness, and transient (temporary) loss of skin color. Some anesthetic agents contain epinephrine, which may cause short-term moderate anxiety, fear or an uneasy feeling, restlessness, shaking, weakness, dizziness, sweating, rapid or abnormal heart beats, increased blood pressure, pale skin, nausea and vomiting, headache, and/or difficulty breathing. These**

symptoms are more likely in people with high blood pressure or an overactive thyroid. Excessive doses of epinephrine may cause severe high blood pressure, stroke, and irregular heartbeats, which can lead to death.

- **Additional Treatment or Surgery Necessary-There are many variable conditions which influence the long term results of laser skin treatments. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with these procedures. Other problems and risks can occur but are even more uncommon. Should problems occur, procedures, surgery, or other treatments may be necessary.**

- **Breach of confidentiality – Although there is always the possibility of a breach of confidentiality, every effort will be made to protect your research data.**

If a complication occurs, you should contact the study doctor immediately who will use her medical judgment to do whatever is necessary to treat you.

The research team is willing to discuss any questions you might have about these risks and discomforts.

5. ARE THERE BENEFITS TO BEING IN THIS RESEARCH STUDY?

You may or may not benefit from this research study. Your condition may get better, stay the same, or worsen. Even though you may not receive any benefit, society may benefit in the future because of what the researchers learn from this research study.

6. WHAT OTHER OPTIONS ARE THERE?

You may choose not to be in this research study. Your choice of whether or not to participate will not affect your clinical care. Lasers including the study laser are FDA approved for treatment of scars. Access to these lasers may also be obtained outside of the study. Other treatment options include laser treatment outside of the study, surgical intervention, and injections of medications such as corticosteroids into the scar.

7. WILL MY INFORMATION BE KEPT PRIVATE?

The results of the research study may be published but your name or identity will not be revealed and your record will remain private. In order to protect your information, Dr. Behshad will assign a study number to your information, and maintain your study documents in locked cabinets in a secure, locked office. Electronic information is kept and transmitted on secure password protected systems with safety firewalls that limit access to authorized study personnel. Digital photographs are maintained on a secure password protected system with safety firewalls and access limited to study personnel and the contracted photography vendor. Information shared will not include your name or contact information.

The Saint Louis University Institutional Review Board (the Board that is responsible for protecting the welfare of persons who take part in research) and other University officials may review your research study records. State laws or court orders may also require that information from your research records be released.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

8. WHAT ARE THE COSTS AND PAYMENTS?

There will be no charge to you for your participation in this study. The facial cleanser will be available at the study site. The investigational product, study-related procedures and study visits that are not otherwise part of your standard of care for your condition will be provided at no charge to you or your insurance company. If antibiotic/antiviral medications are needed, you and/or your insurance company will be responsible for covering this cost. You will not be paid to participate in this study.

9. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you believe that you are injured as a result of your participation in the research study, please contact the research study doctor and/or the Chairperson of the Institutional Review Board as stated in section 10.

You will receive necessary medical treatment in the event that an injury results because of your participation in this research. The University will have the right to determine whether an injury is related to your participation in this study or happened because of your medical condition or other reasons which are not related to this study. If the injury is due to participation in the research, you will not have to pay for the cost of this treatment unless your injury is due to your own failure to follow the study doctor’s instructions. There are no plans for Saint Louis University to pay for the costs of any additional care. You have not waived your legal rights by signing this form. If you have questions, please call the Saint Louis University General Counsel's office at 314-977-5767.

10. WHO CAN I CALL IF I HAVE QUESTIONS?

If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may call Dr. Ramona Behshad at 977-9721. You may also reach the study team at 314-256-3454. For questions after hours, you may call the Saint Louis University switchboard at 314-577-8000 and ask for the dermatologist on-call. That doctor will know how to contact a member of the research team.

If you have questions, concerns or complaints about your rights as a research participant and would like to talk to someone not on the research team, please contact the Saint Louis University Institutional Review Board (IRB) at 314-977-7744 or irb@slu.edu.

11. WHAT ARE MY RIGHTS AND WHAT ELSE SHOULD I KNOW AS A RESEARCH STUDY VOLUNTEER?

Your participation in this research is voluntary. You may choose not to be a part of this research. There will be no penalty to you if you choose not to take part. You may leave the research study at any time. You may refuse to participate or may withdraw from this study at any time without penalty or loss of any rights or benefits to which you are otherwise entitled. The research study doctor or research study staff will let you know of any new information that may affect whether you want to continue to take part in the research study.

If you decide to withdraw from the study you should contact the study staff immediately. If you decide to withdraw, you will be asked to return for a final study visit. If you end the study early, the investigators or study staff may ask you some questions about being in the study. To help you leave the study safely, the investigators may ask you to participate in more tests.

The study doctors can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons, including competitive enrollment - the target number of subjects has entered the study.

12. AM I SURE THAT I UNDERSTAND?

I have read this consent document and have been able to ask questions and state any concerns. I have been asked if I wish to speak directly to the researcher or research study doctor responsible for this research study. The research team has responded to my questions and concerns. I believe I understand the research study and the potential benefits and risks that are involved.

Statement of Consent

I give my informed and voluntary consent to take part in this research study. I will be given a signed and dated copy of this consent document for my records.

_____ _____

Consent Signature of Research Participant (18 and over) Date

_____

Print Name of Participant

SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP
This form is valid only if the IRB's approval stamp is shown below.

I certify that I have explained to the above individual(s) the nature and purpose of the research study and the possible benefit and risks associated with participation. I have answered any questions that have been raised and the subject/patient has received a copy of this signed consent document.

Signature of Consenting Research Team Member	**Date**
First Name / Last Name *Credentials*	
Printed Name of Consenting Research Team Member	

NOTE: The Principal Investigator or Research Team Member that signs here must be authorized in the IRB-approved protocol to obtain informed consent and must sign at the SAME time on the same day as the above signatures are obtained.