UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Fractional photothermolysis for the induction of hair follicles via skin rejuvenation

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STUDY LOCATION(S):
UC Irvine Health – Gottschalk Medical Plaza
UC Irvine Health – Newport Beach
Hewitt Hall

STUDY SPONSOR(S):
UC Irvine School of Medicine
UC Irvine Health Department of Dermatology

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

Study Purpose
The purpose of this research study is to evaluate the effects of laser resurfacing using fractional lasers in helping people with scalp alopecia to increase hair growth.

Study Procedures
This will be a research study involving 50 subjects who will be treated 6-10 times at 2-4 week intervals. Each individual will have half of their head treated with a laser, either the Fraxel DUAL 1550 or Halo, and the other half will be left untreated as a control. At the end of the study, we will treat the untreated side of the head to even it out. Half of the individuals will randomly be assigned to the group to be treated with Fraxel DUAL 1550, and the other half will be treated with Halo by Sciton. Visual observation and digital, photographic, non-invasive imaging will be used to compare the treated and untreated area to assess for differences in number and density of hairs.

Expected Duration
Participation will last approximately 24-48 weeks no more than 1 hour of your time for each visit. The first imaging session will be followed by 5-9 visits that include imaging if you choose to continue your participation and wish to have your untreated side treated by the laser.

Risks of Participation
The more notable risks of participation include potential for additional hair loss, swelling, or redness from treatment with a laser. Other temporary side effects may include minor itching, dry skin, peeling or flaking, and a bronzed skin appearance. There is a limited risk of infection, hyperpigmentation, or scarring.

Benefits to Participants
Taking part in this study may or may not make your health better. While researchers hope that treatment with the fractional laser therapy will promote new hair growth in areas of the head where hair was lost and improve of quality of life measures in comparison to the standard (usual) treatment, there is no proof of this yet. It is possible that there would be no direct benefit.

Benefits to Others or Society
This study will help researchers learn more about the use of fractional photothermolysis laser therapy to treat hair loss and it is hoped that this information will help in the treatment of future patients with conditions like yours.

Alternative Procedures or Treatments
If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:

- Getting no treatment
- Getting standard treatment for your condition without being in a study.
- Getting a different experimental treatment/taking part in another study.
- Depending on the type of alopecia, your doctor may suggest using a medication such as Minoxidil.
- Hair transplant surgeries are also an option that we can provide information about if interested.

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to evaluate the effects of laser resurfacing using fractional lasers in helping people with scalp alopecia to increase hair growth. A fractional laser is a laser that directs an intense burst of laser energy on skin. The treatment deposits heat deep into the dermis to tighten skin and stimulate collagen remodeling. Fractional lasers were originally designed as a form of laser therapy to treat wrinkles and scars. Although the link between laser treatment and hair growth is not clear and the exact mechanism still unknown, there is evidence to support that laser irradiation (heat) holds potential for the induction of hair follicles in subjects with alopecia. Laser therapy has been reported to increase hair growth and activate hair follicles. The lasers rejuvenate skin, and hair follicles are a part of skin, along with nails, so through the rejuvenation of skin, these things also may get rejuvenated.

The types of fractional lasers we plan to use include the ***Fraxel DUAL 1550*** and ***Halo***.
The use of the Fraxel DUAL 1550 and Halo lasers to treat alopecia is investigational. This means that the Food and Drug Administration (FDA) has not approved either laser for this specific purpose. Both lasers are either cleared or approved (respectively) by the FDA for other purposes, such as skin resurfacing for treatment of the hands, face, and body.

Fraxel DUAL 1550: 

Halo: 

This will be a research study involving 50 subjects who will be treated 6-10 times at 2-4 week intervals. Each individual will have half of their head treated with a laser, either the Fraxel DUAL 1550 or Halo, and the other half will be left untreated as a control. At the end of the study, we will treat the untreated side of the head to even it out. Half of the individuals will randomly be assigned to the group to be treated with Fraxel DUAL 1550, and the other half will be treated with Halo by Sciton. Visual observation and digital, photographic, non-invasive imaging will be used to compare the treated and untreated area to assess for differences in number and density of hairs.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 50 participants will take part in the research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
- ∞ Must be between the age of 18-90
- ∞ Diagnosed with hair loss on scalp by a dermatologist
- ∞ No other treatments for hair loss have been done in the past 1 month
- ∞ No evidence of spontaneous hair regrowth
- ∞ Good health
- ∞ Must agree to comply to study treatment
- ∞ Healthy scalp without neoplasm
- ∞ Scarring and nonscarring alopecia acceptable

Exclusion Requirements
- ∞ Any visible signs of neoplasm (an abnormal tissue growth), infection, inflammatory disease of scalp
- ∞ History of photosensitivity, impaired wound healing, chronic liver or kidney disease
- ∞ No concurrent use of Minoxidil, platelet rich plasma, or light devices for hair growth
- ∞ Has not initiated use of Finasteride or Spironolactone in the 3 months preceding the study
- ∞ Pregnancy (pregnancy will be determined by verbal confirmation)

HOW LONG WILL THE STUDY GO ON?
The first imaging session will be followed by 5-9 more visits that include imaging if you choose to continue your participation and wish to have your untreated side treated by the laser. The total length of the study will be 24-28 weeks.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?

The following procedures will occur before you participate in this study:

1. You will be explained that the laser therapy and observations will have research purposes only.
2. If you decide not to participate in this study, your care at UCI or any other provider will not be affected. You will receive the standard of health care whether you choose to participate in this study or choose not to.
3. You will be given consent forms to either sign or bring home for consideration.

Please ask for more information about the study at any time.

The following procedures will occur during a treatment session:

1) Your study doctor will identify the scalp areas that will be treated on the treatment side of your scalp. The other half of the scalp will be left untreated for comparison.
2) Both the scalp area that will be treated and the area that is not related will be photographed. Facial images that can identify you will not be photographed.
3) The area will be numbed with a topical anesthetic, and treated with a fractional laser (Fraxel restore or Sciton Halo) with low energy and high density settings.
4) The laser settings used, which include energy and density of laser treatment per centimeter squared, will be similar for each person at each treatment session.
5) Digital, non-invasive photographs will be taken of the treated and untreated areas at the end of treatment.
6) The hairs will be counted at each visit on both the treated and untreated areas.
7) If you feel uncomfortable during the treatment, you may tell the researcher to stop treating immediately.
8) Your medical record will be accessed by Dr. Mesinkovska and members of her research team. The information accessed includes: medical record number, birthdate, gender and diagnosis of the skin condition. If your medical doctor is not a UCI-provider, this information will be shared, with your permission with the UCI research team responsible for this study. No additional information will be collected.
9) You may be asked to participate in more than one treatment session but not more than ten. You have the option of refusing participation in additional sessions.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?
You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. The researchers may give you medicines to help lessen side effects. Many side effects go away soon after the procedure. In some cases, side effects can be serious, long lasting, or may never go away

You should talk to the research team about any side affects you experience while taking part in the study.

Risks and side effects related to the fractional lasers include those which are:

Breach of Confidentiality
There is a small chance of a breach of confidentiality involving research data. All identifiable information that will be collected about the subject will be removed and replaced with a code. A list linking the code and subject identifiable information will be kept separate from the research data.

General Laser Risks – Fraxel DUAL and HALO
You may have side effects while in this study. Everyone taking part in the study will be watched carefully for any side effects. However, researcher do not know all the side effects that may happen during the treatment and follow up time periods. Side effects may be mild or very serious and the researchers may give you medicine to help lessen side effects. Fractional laser treatment, also known as non-ablative resurfacing, is commonly used for rejuvenation of the skin to improve quality, tone, and texture. Many of the side effects associated with treatment with this kind of laser are self-limited and go away on their own a few days after the treatment is done. Everyone reacts differently to the treatment, and some may experience more side effects than others.

Note: With the use of either laser there is the potential for additional hair loss.

You should talk to the research team about any side affects you experience while taking part in the study.

Risks and side effects related to the laser treatments are discussed below:

Fraxel DUAL
Swelling and redness are the most common side effects from a Fraxel DUAL 1550/1927 treatment. Any swelling is typically minimal and subsides within a day or two, and any redness typically fades within a few days. In rare cases these signs of inflammation can persist for weeks, if that is the case, please alert your study doctor. Other temporary side effects may include minor itching, dry skin, peeling or flaking, and a bronzed skin appearance. There is a limited risk of infection, hyperpigmentation or scarring. Hyperpigmentation is more common in darker pigmented skin types and can be alleviated with topical retinoid or glycolic acid. The intensity and duration of side effects depend on the aggressiveness and depth of a treatment and on your particular healing characteristics. Your study physician will provide specific instructions about what to expect and how to minimize any side effects. Your study physician will also prescribe you appropriate medication if your side effects are deemed serious.

As noted above, after treatment with the Fraxel laser, the skin is typically red or pink and may be covered with a fine crust. The treated areas are usually kept moist with cool soaks and an application of healing ointment. Creams or bandages applied to healing skin can sometimes worsen acne or irritate the skin further. The treated sites must be protected from sun exposure after the procedure. Once healing is complete, sunblock should be applied. In some cases, a pink surface color may remain for several days. Make-up can be worn over treatment areas typically in one week post procedure.

Additional hair loss may occur.

Halo
With a topical anesthetic (Pliaglis cream which includes lidocaine and tetracaine) and integrated cooling technology, most patients experience very little discomfort. Most patients describe the treatment as a feeling of heat with occasional prickling sensations but are generally comfortable. After the treatment, most patients will continue to feel warm for an additional 15 to 30 minutes, or a bit longer with deeper treatment levels. Cooling measures with moist cloths and fans can sooth these symptoms.

For the first 24-48 hours you should keep your skin protected from the sun and further swelling according to your research doctor’s instructions. You may be prescribed medication to calm persistent inflammation if it causes significant discomfort. After the first day, depending on the depth of your treatment and the

amount of residual swelling, you should be able to go about your normal activities. After the first 24 hours your skin may begin to peel, look darker, and itch. You will be able to put makeup on treated areas. Noticeable changes in skin rejuvenation may not be present for up to a week after treatment.

Additional hair loss may occur.

Unknown risks:
There may be risks related to the research that we don't know about yet. However, you will be informed of any additional risks to which you may be exposed, and any changes that are made to the study, as a result of any newly-identified risks.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation
You will not be compensated for your participation in this research study.

Reimbursement
You will not receive reimbursement for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you or your insurer/third party payer for your participation in this study.

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

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor, or billed to you or your insurer just like other medical costs, depending on a number of factors.

The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.

Data Storage

Research data will be stored electronically on a secure computer in an encrypted file. Only authorized individuals will have access to it. There will be no hardcopy data.

Study data might be processed, analyzed, and kept on laptops besides the desktop computer, but subject identifiable data will not be stored on portable devices.

Data Retention

In accordance with UC Office of the President policy, information will be retained for 10 years after the end of the calendar year in which the research is completed.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized UCI personnel, the study sponsor, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Future Research Use

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

ClinicalTrials.govClinicalTrials.gov is a Web site that provides information about clinical trials. 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.

Investigator Financial Conflict of Interest

No one on the study team has a disclosable financial interest related to this research project.

Future Contact
The study team would like your permission to contact you for future research. Please initial your level of permission below:

_____ Yes, UCI researchers may contact me in the future to ask me to take part in other research studies.

_____ No, UCI researchers may **not** contact me in the future to ask me to take part in other research studies.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact the UCI Institutional Review Board by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 160 Aldrich Hall, Irvine, CA 92697-7600.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep.
Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

_____ _____
Subject Signature **Date**

_____
Printed Name of Subject

_____ _____
Signature of Person Obtaining Informed Consent **Date**
(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)

_____
Printed Name of Person Obtaining Informed Consent

A witness signature is required on this consent form only if: (Researchers: check which one applies)

IMPORTANT! If no witness signature is required, this witness signature section of the consent form may be left blank.

☐ Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐ The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐ The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐ The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
Witness Signature **Date**
Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 160 Aldrich Hall, Irvine, CA 92697-7600.

University of California Irvine Health
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy): Fractional Photothermolysis for the Treatment of Hair Loss

Principal Investigator Name: Natasha Mesinkovska, MD, PhD

Sponsor/Funding Agency (if funded): Department

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that health care providers can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UC Irvine Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing your health care provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☒ Entire Medical Record

☐ Ambulatory Clinic Records
☐ Progress Notes
☐ Other Test Reports
☐ Other (describe):
Type Here
(Description of Other Health Information)

☐ Lab & Pathology Reports
☐ Dental Records
☐ Operative Reports
☐ Discharge Summary
☐ Consultations

☐ Emergency Department Records
☐ Financial Records
☐ Imaging Reports
☐ History & Physical Exams
☐ Psychological Tests

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

_____I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

_____I agree to the release of HIV/AIDS testing information.

_____I agree to the release of genetic testing information.

_____I agree to the release of information pertaining to mental health diagnosis or treatment.

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's representatives, or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;

4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____

Subject's Name (print)—*required*

_____ _____

Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____ _____

Parent or Legally Authorized Representative's Name (print) Relationship to Subject

_____ _____

Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____

Witness' Name (print)

_____ _____

Witness' Signature Date