Consent Form (includes HIPAA Authorization)

Title of Research Study: ***Effect of Mechanical Intervention on the Scalp Microbiome: Setting the Stage for the Future Management of Cicatricial Alopecias***

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Ronda Farah, MD Departmental Affiliation: Dermatology Phone Number: 612-625-8625 Email Address: rfarah@umn.edu	Study Staff: Irmina Wallander Phone Number: 612-624-5721 Email Address: dermresearch@umn.edu

If your doctor is also the person responsible for this research study, please note that she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by the American Academy of Dermatology.

Key Information About This Research Study

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

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have a healthy scalp and are between the ages of 18-50 years old.

What should I know about a research study?

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

Approved for use by UMN IRB
Effective on 11/22/2023
IRB Study Number: STUDY00014160

- You can ask all the questions you want before you decide.

Why is this research being done?

The scalp microbiome is made up of bacteria, viruses, and fungi that live on the scalp, and it is an important part of overall scalp health. The purpose of this research study is to test if cleansing the scalp with the Venus Glow™ changes the composition of the scalp microbiome and improves scalp health.

The Venus Glow™ has been cleared by the FDA for use as a cosmetic treatment, but its use in this study is investigational because we are modifying the settings to optimize scalp health. Water will be applied directly onto the scalp using two small jets, while a rotating tip micro-massages and exfoliates the scalp, and a small adjustable vacuum removes any debris from the area.

How long will the research last?

We expect that you will be in this research study for approximately 2.5 weeks.

What will I need to do to participate?

You will be asked to have two treatments with the Venus Glow™ within two weeks. . Approximately 3-6 days after the last treatment, you will have a final follow-up visit. The study staff will also photograph and collect a swab of your scalp to analyze changes in your scalp microbiome and health at all 3 of the study visits.

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

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

Potential risks of using the Venus Glow™ device to cleanse your scalp:

- Irritation
- Redness
- Headache
- Itching
- Tingling
- Abrasion of the skin

Privacy & confidentiality risks: There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include an improvement in scale and/or oiliness of your scalp.

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

There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

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

How many people will be studied?

We expect about 25 people will be in this research study.

Approved for use by UMN IRB
Effective on 11/22/2023
IRB Study Number: STUDY00014160

What happens if I say "*Yes, I want to be in this research*"?

If you choose to participate in this study, you will attend three in-person visits, each lasting approximately 30-45 minutes. It is important that you do not wash your hair with shampoo or use or receive any chemical or heat treatments to your hair during the one-week treatment period between the first and second treatments, but you can wet your hair during this time. After the treatment period, you can resume your normal hair care routine.

Treatment 1 (Baseline Visit):

- The study staff will discuss this consent form with you.
- The study staff will collect your demographic information and ask you questions about your medical history.
- You will complete questionnaires about your current hair and scalp care practices, skin type, and hair type.
- The study staff will photograph and swab the mid-frontal region of your scalp on both the right and left sides. ○ To identify which area(s) of your scalp is in the photograph, the study staff will draw a small mark on your scalp using a purple surgical marker that will wash off on its own within a few days.
- The right side of your scalp will be treated with the Venus Glow™ device.
- After the treatment, the study staff will re-swab the right side of your scalp.

Treatment 2:

This visit will take place approximately 7 days after your first treatment.

- The study staff will ask you about any possible adverse events from your previous treatment(s), such as headache, redness, tingling, etc.
- The study staff will photograph and swab the right and left mid-frontal regions of your scalp.
  - The study staff will again draw a small mark on your scalp to identify the area(s) being photographed, which will wash off on its own within a few days.
- The right side of your scalp will be treated with the Venus Glow™ device.
- After the treatment, the study staff will re-swab the right side of your scalp.

Follow-Up Visit:

This visit will occur approximately 3-6 days after your last treatment.

- The study staff will ask you about any possible adverse events from your previous treatment(s), such as headache, redness, tingling, etc.
- The study staff will photograph and swab the right and left mid-frontal regions of your scalp.

If you miss your follow-up visit and are unable to reschedule, a study staff member may call you for a brief follow-up over the phone.

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

If you take part in this research, you will be responsible for attending the study visits and following the instructions of the study team.

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

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

Approved for use by UMN IRB
Effective on 11/22/2023
IRB Study Number: STUDY00014160

Can I be removed from the research?

It's possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed. Possible reasons may include:

- Failing to follow instructions from the study staff
- If you are no longer eligible to participate
- If the study doctor determines that it is in your best interest to stop participating.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

Hormonal and physical changes associated with pregnancy and breastfeeding could impact the accuracy of the data and the research results. You should not be or become pregnant while in this research study. You should also not participate in the study if you are breastfeeding.

If you are sexually active woman of child bearing potential, you should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable, but least effective, methods of birth control include male condoms (with or without spermicide) and female condoms.

If you become pregnant while participating in this research study, it is important that you tell the study doctor or other research team member immediately. You might be required to stop participation in this study; however, other clinical care options will be discussed with you at that time if necessary.

If you are considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. If you or your partner become pregnant while participating in this research study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other clinical care options will be discussed with you at that time if necessary.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you. If your study visits are at the PhillipsWangensteen Building at the University of Minnesota or M Health Fairview Clinics and Surgery CenterMinneapolis, parking vouchers for the Delaware patient parking ramp will be provided. If your study visits take place at the M Health Fairview Maple Grove Clinic, you will not need a parking voucher as parking in the clinic lot is free.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Approved for use by UMN IRB
Effective on 11/22/2023
IRB Study Number: STUDY00014160

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☐ My genetic testing records _____ (initial)

☐ My mental health diagnosis/treatment records ____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

Approved for use by UMN IRB
Effective on 11/22/2023
IRB Study Number: STUDY00014160

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data and specimens when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

Approved for use by UMN IRB
Effective on 11/22/2023
IRB Study Number: STUDY00014160

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.

Approved for use by UMN IRB
Effective on 11/22/2023
IRB Study Number: STUDY00014160

- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to $30 for your time and effort. You will receive $10 for each visit you complete. If you withdraw from the study at any point, you will still be paid for the study visits you have already completed.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive a cardholder agreement. Be sure to read all of this information for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, and MasterCard, will be given your name and address and social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire and MasterCard will not receive any information about your health status or the study in which you are participating.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes,	**No,**
I agree	**I disagree**

The investigator may contact me in the future to see whether I am interested in participating in other research studies by Dr. Farah and her research collaborators.

_____ _____

Signatures:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Approved for use by UMN IRB
Effective on 11/22/2023
IRB Study Number: STUDY00014160