PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: Combination Topical Cysteamine and Fractional 1927nm Low-Powered Diode Laser

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SPONSOR: Skin of Color Society

INTRODUCTION

We are asking you to be in a research study. Please read this consent form carefully and completely. You should not join this study until all your questions are answered. A person who takes part in a research study is called a research subject, or research participant. This consent form will help you decide if you want to be a subject in this research study. If you are not completely truthful with your study doctor regarding your health history, you may harm yourself by participating in this study. The study is being conducted for Skin of Color Society.

Things to know before deciding to take part in a research study:

- Someone will explain this research to you.
- This form summarizes that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled. If you decide not to take part in this study, your doctors will continue to treat you.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- Information from your medical records will become part of the research record. Your medical records may be looked at and/or copied by sponsor of this study and government agencies or other groups associated with the study.
- Your will be billed for any standard medical care you receive during the research study.
- If you take part in this research study, you will be given a copy of this signed and dated consent form.
- If you take complete the study, you will receive a monetary payment in the amount of $75.00

BACKGROUND:

You are being asked to participate in this research study because you have evidence of melasma on your face. Melasma is a common pigmentary condition characterized by brown spots on sun-exposed areas of the face. Patients are often bothered by the appearance of melasma as seen by uneven skin color (pigmentation) near the surface of the skin.

Treatment of melasma can be challenging as many patients have had limited success with various topical skin-lightening and brightening agents and lasers. Melasma can also significantly impact patients' quality of life leading to feelings of frustration, embarrassment, and depression related to their condition.

Topical cysteamine is a safe and well tolerated medication which has been shown to be effective in the treatment of melasma. Separately, the Clear + Brilliant® Touch laser system, contains a 1927-nm handpiece (Clear + Brilliant Permea®) which helps improve uneven skin tone and other issues related to hyperpigmentation. In this study both cysteamine and the Clear + Brilliant laser system will be used. Since the combination of this device and this topical medication has not been evaluated for treatment of melasma, it's use in this study is investigational.

In this document, you may see the terms "treatment" and "treatment period". These are terms used in research studies and these terms do not mean that you will be receiving medical treatment for any condition. These terms apply to the investigational study device and parts of the study where you will be receiving this study device.

PURPOSE

The purpose of this study is to evaluate the effect of topical cysteamine in combination with Clear & Brilliant laser in the treatment of melasma on the face. There have been no studies to date looking at this laser in combination with this topical medication in the treatment of melasma.

Approximately 20 people age 18 to 74 years old, inclusive, will participate in this study.

LENGTH OF PARTICIPATION

Your participation in this study will last approximately 12 weeks and include 4 study visits to the study center.

WHAT WILL HAPPEN DURING THE STUDY?

If you participate in this study, you will be asked to use topical 5% cysteamine daily to your entire face per the product guidelines (apply uniformly to areas with melisma nightly for 15 minutes then wash off). You will also be treated on half of your face with the Clear + Brilliant® Touch laser system. Before each laser treatment, you will be asked to remove any jewelry and any hair in the area to be treated. The skin will be cleaned by the study staff. Each study treatment will involve four passes of the laser handpiece at a high setting over half of the face. Treatments will be repeated monthly for a total of 3 treatments. You will be photographed before treatment and at each follow-up visit. You will have three treatments of the test areas four weeks apart, except

when deemed inappropriate by the study doctor (for example due to persistent redness (erythema) or adverse events which are clinically significant in the opinion of the study doctor). A follow-up visit will also be scheduled 12 weeks after the first laser treatment. Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document.

Study Visits

Visit 1 (Screening and Initial Treatment Visit)

The study staff will perform the following procedures at this visit:

- Ask you to give personal information, such as name, date of birth, race and ethnicity
- Review your medical and dermatology (skin) history, including history of previous treatments to the area being treated
- Review your past and current medications and skin care products
- See how tall you are and how much you weigh
- If you are woman and can have children, urine will be collected and tested to see if you are pregnant. The study doctor or study staff will tell you if your pregnancy test results are positive. The results of the pregnancy testing must be negative in order for you to be in the study
- Identify and examine the area of your face (for example, which half) that will be treated with the Clear & Brilliant® Touch laser system
- Take photos of your face
- Perform an assessment of your melisma
- Perform treatment using the Clear and Brilliant® Touch laser system
- Provide cysteamine to be used daily as instructed. You should keep this cream out of the reach of children.
- Schedule the next study visit

Visit 2 and 3 (Week 4 and 8)

The study staff will perform the following procedures at this visit:

- Assess side-effects of treatment
- See how tall you are and how much you weigh
- Take photos of your face
- Perform treatment on the previously selected area of your face using the Clear and Brilliant® Touch laser system
- Schedule the next study visit

Visit 4 (Week 12/End of Study)

The study staff will perform the following procedures at this visit:

- Assess side-effects of treatment
- See how tall you are and how much you weigh
- Take photos of your face

- Perform a melasma assessment
- Ask you to complete a post-treatment questionnaire

Pregnancy / Birth Control

Laser and light-based therapies for cosmetic use have not been studied in women who are pregnant and therefore should not be used during pregnancy as it may involve unknown risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing child. Therefore, if you are pregnant, planning to become pregnant or are breastfeeding a child, you cannot participate in this study.

In order to reduce the risk of pregnancy, you must use an effective method of birth control while you are participating in this study. If you are already using a method of birth control, the study doctor or study staff will discuss with you whether your current method of birth control is acceptable for use during this study.

If, during this study, you become pregnant, you should notify the study doctor as soon as possible. Your participation in this study will be ended.

A urine pregnancy test will be administered on Visit 1/ Screening (Week 0).

Laser Parameters/Application:

Following 30 minutes of topical 30% lidocaine application (a numbing agent), half of your face will be treated with Clear & Brilliant® Permea 1927 nm handpiece.

Photographs:

Photographs will be taken at each visit prior to treatment to evaluate healing time, clinical improvement, as well as any side effects. The study staff will take photographs of your face. There will be no additional compensation if you are photographed.

The study doctor will use the photographs for presentations and publications.

The sponsor also may use the photographs for marketing or other commercial purposes that include, but may not be limited to print, broadcast media, internet publications, presentations or journals. There are no plans to share with you any profits that may be generated by the use of your photographs; however, you do not give up any legal rights you may have by participating in the photography portion of this study.

If you do not permit the study staff to take photographs of you as described above, then you will not be able to participate in this study. If you withdraw from the study or withdraw your permission for the study staff to take photographs of you, you may no longer participate in the study and your photographs will no longer be used, except to the extent that the photographs have already been published and appear in print, broadcast media, Internet publications, presentations or journals.

RISKS, SIDE EFFECTS AND/OR DISCOMFORTS:

The risks to you from participating in this study are the same as those you would experience from undergoing any dermatological laser treatment, such as for the removal of pigmented or vascular lesions. Eye injury, due to the use of the laser, is a risk to the subject and the operator. Blistering, edema (swelling), erythema (redness), and mild to moderate local pain are typical reactions to topical laser treatments. A lesser possibility exists for hyperpigmentation (darkening of the skin), hypopigmentation (lightening of the skin), scarring, and/or infection. These conditions may or may not resolve over time.

Clear & Brilliant® Touch is a non-invasive laser treatment system that was approved for use by the United States Food and Drug Administration (FDA) for the treatment of skin rejuvenation in 2011. The most common side effects of Clear & Brilliant include:

- Prolonged redness
- Discomfort
- Itching/dryness
- Herpes simplex (cold sore) reactivation
- Infection

Other possible side effects of the approved use of Clear & Brilliant® Touch include:

- An increase or decrease in the pigmentation (darkening or lightening of the skin).
- Localized swelling
- Oozing (seeping)
- Crusting (skin thickening)
- Erosions (loss of skin)
- Bleeding
- Scarring

These side effects usually get better without problems, but it is not yet known whether they will get better without problems in this study, since this study will use Clear & Brilliant® Touch in a way that is different from the approved purpose.

Other side effects

Before the laser procedure, a topical numbing medication will be applied to your skin. Possible side effects from this medication include:

- Mild irritation where the medication is applied
- Numbness in places where the medicine is accidentally applied
- Allergic reaction. Symptoms of any allergic reaction can include a rash, hives, itching, and/or difficulty breathing, closing of the throat, or swelling of the lips, tongue, or face. Rarely it can cause death. **If you think you are having a severe allergic reaction, dial 9-1-1 and seek medical attention immediately.**

Throughout the study, you will be asked to use cysteamine topical cream daily at home. Possible side effects from this medication include:

- Temporary heating up or burning sensation and redness that resolves within 30 minutes
- Mild irritation where the medication is applied

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study solution or study device.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

RISK MANAGEMENT:

You will be followed closely during the course of the trial and will have access to the study doctor or study staff at all times by an after-hours telephone and/or pager numbers. You will be required to wear suitable eye protection, along with the study doctor and study staff, while the laser treatment is given. A local anesthetic may be given before treatment to minimize pain and/or discomfort resulting from laser treatment.

BENEFITS:

You may or may not show improvement of your melasma. There is no guarantee that you will benefit from your participation in this study. Results from this study may benefit others in the future.

COSTS AND COMPENSATION:

You will be compensated $75.00 for your participation in this study.

The treatment you receive in this study will be provided to you at no cost. If any of the previously mentioned side effects occur, you will be responsible for purchasing the supplies you need to care for the areas that are affected, including the sunscreen. All the supplies can be purchased at your local drug store without a prescription.

COMPENSATION FOR INJURY:

If you experience any of the side effects described under RISKS AND DISCOMFORTS, or if you are injured in any way as a result of participation in this study, medical care will be provided to you by the study doctor. Union Square Laser Dermatology is a full service medical facility, with a full service staff, trained in basic emergency first aid. In the event of a serious adverse event, such as a severe allergic reaction, Union Square Laser Dermatology will administer primary emergency first aid care. However, if you require further assistance outside of Union Square Laser Dermatology, the cost of the medical care will be your responsibility and you must arrange

for any reimbursement or coverage from your insurance company. If you believe you have any study related illness, adverse event, or injury, you must notify the study doctor as soon as possible. To ask questions about this, talk to the study doctor or study staff.

You do not waive any of your legal rights by signing this form.

CONFIDENTIALITY:

Your medical records, in connection with this study, will be kept as confidential as possible under local, state and federal laws. The Food and Drug Administration and the sponsor (Skin of Color Society) who funds the study are permitted to have access to your medical record and to the data produced by this study, for audit purposes. However, they are required to maintain confidentiality. The Sterling Institutional Review Board, which is a committee that has reviewed this research project to help ensure that the rights and welfare of the participants are protected and that the study is carried out in an ethical manner, may also inspect your medical records.

If the data is used for publication in medical literature or for teaching purposes, no names or other identifiers will be used. Photographs will be taken of small areas and are unlikely to reveal your identity.

AUTHORIZATION TO COLLECT, USE AND DISCLOSE YOUR MEDICAL INFORMATION

As a part of this research, records that contain information or data about you and your health may be collected and used. Under the privacy laws, you have the rights to decide who can use your protected health information (called PHI). When you sign this form, you are saying that you will allow the use of your protected health information for this study.

The information that will be collected about you as a part of this research includes:

- Name
- Address
- Telephone number
- Birth date
- Race
- Sex
- Family medical history
- Allergies
- Medications you take (current and past)
- Results of study tests and study procedures
- Other information from other doctors' offices, clinics, and/or hospitals that is needed for the study

Information collected about you for the study will be kept in a research file that is separate from your medical chart. You will not be able to see your research file until after the end of the study.

The following groups may review and use your study information. They may review your study information to make sure that it is correct. They may also review your information to make sure that the study is being conducted properly.

- The study sponsor (or sponsor representatives such as monitors and/or auditors)
- The U.S. Food and Drug Administration (FDA)
- Sterling Institutional Review Board (IRB)
- The Department of Health and Human Service (DHHS)
- Other government agencies in other countries
- Other doctors, health care professionals or research staff who are involved in the study

Your study information may be released to the groups listed above. If your study information is reviewed by these people, they may need to see your entire medical record; it is possible that your Social Security number may be included in the records reviewed. Because of this, it cannot be assured that your confidentiality will always be protected. It is possible that your information will be shared (re-disclosed) in a way that it would no longer be protected. However, this access to your records will be granted without violating your confidentiality to the extent permitted by applicable laws and regulations. By signing this form, you are authorizing this access to your records.

This permission (also called an authorization) will have no end date.

You have a right to see your study records; however, you will not be able to see your study records until after the study has ended.

You may also take away (or withdraw) your permission for the use of your protected health information at any time. If you choose to withdraw your permission, you must write your study doctor a letter.

The study doctor's mailing address is UnionDerm, 19 Union Square West, New York, NY 10003. The study doctor will still be able to use the health information collected about you before you withdrew your permission. Information that has already been sent to the sponsor of the study cannot be taken back.

If you withdraw your permission after you have entered the study, you cannot continue participating in the study. If you refuse to give permission or withdraw your permission, your medical care and your relationship with the health care providers at the study center will not be affected.

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.

VOLUNTARY PARTICIPATION/WITHDRAWAL OF PARTICIPATION:

Your participation is voluntary, and you may refuse to participate or may withdraw consent and discontinue participation in the study at any time without penalty or loss of benefits to which you

are otherwise entitled at Union Square Laser Dermatology. The study doctor may terminate your participation in this study at any time after he/she has explained the reasons for doing so and has helped arrange for your continued care by your own physician, if this is appropriate. Anticipated circumstances under which your participation may be stopped by the study doctor without your consent include:

- if it is deemed to be in the best interest of your health and welfare.
- if you have severe or unacceptable side effects.
- if you fail to follow instructions.

QUESTIONS

If you have questions, concerns or complaints about the research study or you experience a research-related injury, please contact Dr. Chapas or the study staff at 212-366-5800 or 617-515-7867 (both 24 hours).

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free) or info@sterlingirb.com.

CONSENT:

My signature indicates the following:

- I have read and I understand the information outlined above.
- I have discussed my questions with the study doctor and the staff.
- I will receive a signed copy of the consent form.
- I voluntarily agree to participate in this study.
- By signing this consent form, I have not given up any legal rights.

_____ _____
Participant's Name (printed) Age

_____ _____
Participant's Signature Date

I certify that I have made the disclosures referred to above and have given the patient the opportunity to ask questions.

_____
Study Doctor's Name

_____ _____
Study Doctor's Signature Date