Title of research study: Pilot study for the use of photodynamic therapy in the treatment of seborrheic dermatitis

Investigator:

Principal Investigator: Nasim Fazel, MD, DDS, MAS, Department of Dermatology
Co-Principal Investigator: Raja Sivamani, MD, MS, CAT, Department of Dermatology

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are generally healthy, have seborrheic dermatitis of the face, do not have any other diseases of the skin, and are 18 years of age or older.

What should I know about a research study?

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
  - Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study.
  - Medical treatment, if any, that is available for complications.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team (Dr. Nasim Fazel, Dr. Raja Sivamani, Parastoo Davari) at 916-734-6876, 916-733-5445, or 916-734-6760. You may also call the UC Davis Dermatology clinic at 916-734-6111 or the UC Davis Medical Center Hospital Operator at 916-734-2011 and reach the on call dermatologist 24 hours a day.

For IRB Use

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This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/IRBAdmin.You may talk to a IRB staff member at (916)703-9151, IRBAdmin@ucdmc.ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

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

Why is this research being done?

This is a research study conducted by Nasim Fazel, MD, DDS, MAS and Raja Sivamani, MD, MS, CAT from the Department of Dermatology and funded by the Department of Dermatology. The main goal of a research study is to learn things to help patients in the future. No one can guarantee that a research study will help you.

This study involves the treatment of seborrheic dermatitis of the face. Seborrheic dermatitis can be treated with a wide variety of topical medications including topical steroids and antifungals. Traditionally, patients with seborrheic dermatitis have to use topical medications long-term as these treatments do not "cure" seborrheic dermatitis, but rather keep it in remission. This study examines a new treatment method using a chemical called aminolevulinic acid (ALA), which is placed on the skin followed by exposure to blue light.

This research study is a pilot study. Participating in a pilot study may not benefit you and should not be considered a treatment. The purpose of a pilot study is to conduct a small-scale clinical study to investigate the clinical efficacy of photodynamic therapy in the treatment of seborrheic dermatitis and how the treatment may alter the bacteria normally found on the skin with short-term use.

How long will the research last?

We expect that you will be in this research study for 3-4.5 months.

How many people will be studied?

We expect about 12 people here will be in this research study.

What happens if I say yes, I want to be in this research?

If you decide to take part in this study, you will be asked to:

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Week	**What you do**
Prior to starting the study	You will be asked to read and sign this consent form and a photo consent form giving the research team permission to use photographs for publications/conferences/training purposes. You will also be asked to sign a medical record release form. Please refrain from the use of any topical medications, soaps or lotions on your skin while in this study, except as provided by the study team. If you are prescribed topical, oral, intramuscular or intravenous antibiotics at any time during the study, please inform the researchers.
Week 0	If you are using any topical medications and would like to participate in the study, you may do so after a **2-week washout period.** If you are using systemic medications, you may enroll in the study after a **4-week washout period.** Your prescribing physician will need to agree to this washout so you can be in this study. If you are a woman and have recently changed your birth control method, you may participate in the study after using the same method for a period greater than 2 months. Use only Dove™ soap to the face for the duration of this study and use the provided moisturizer and sunscreen as needed.
Week 2-10	**Visit 1:** 1. Urine pregnancy test if you are a woman. If you are postmenopasual or do not have a uterus, then you will be exempted from pregnancy testing. 2. Facial photography for SASI-F grading and erythema and scale grading 3. Swabs of facial sites 4. Measurement of facial sebum production rates with SebuMeter® 5. Application of ALA to treatment side and placebo to control side with one hour incubation 6. Expose to blue light per UC Davis Dept of Dermatology standard protocol

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2-4 weeks later	**Visit 2:** 1. Urine pregnancy test if you are a woman. If you are postmenopasual or do not have a uterus, then you will be exempted from pregnancy testing. 2. Facial photography for SASI-F grading and erythema and scale grading 3. Measurement of facial sebum production rates with SebuMeter® 4. Application of ALA to treatment side and sham ALA placebo to control side with one hour incubation
2-4 weeks later	**Visit 3:** 1. Facial photography for SASI-F grading and erythema and scale grading 2. Swabs of facial sites 3. Measurement of facial sebum production rates with SebuMeter®
End of study	

In this study, we are not following the FDA application guidelines.

During the study, you will interact with the research team. All visits will take place at the UC Davis Dermatology Clinic in Sacramento. Each visit will last approximately 1.5 hours.

Only one half of your face will receive the treatment with ALA and blue light. After the third visit and completion of this study, patients have the option of being seen by their selected Dermatologist, to continue treatment for the untreated side of face as standard of care. Standard of care and other routine costs will be billed to patient or the patient's insurance carrier, Medicare, or Medi-cal, where appropriate.

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

If you take part in this research, you will be responsible to:

-- Use only Dove™ soap to your face during the entire length of the study period.

-- Refrain from the use of any topical medications, soaps or lotions to your skin while in this study other than the products provided by the study team.

-- Inform the researchers if you are prescribed oral antibiotics at any time during the study.

-- Come to UC Davis Dermatology Clinic in Sacramento for three office visits, two of which involve treatment as described above.

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

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You may decide not to take part in the research and it will not be held against you.

Instead of being in this research study, your choices may include: topical steroids or topical antifungal medications for the treatment of seborrheic dermatitis.

The important risks and possible benefits of these alternatives include:

Allergy or irritation to topical medications

Cost of long-term use of topical medications

Topical steroids and antifungals may help to improve seborrheic dermatitis.

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

You can leave the research at any time and it will not be held against you.

Tell the Researcher if you are thinking about stopping or decide to stop so any risks from the topical medications can be managed safely. Another reason to tell the Researchers that you are thinking about stopping is to discuss what follow-up care and testing may be important for you.

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

You may have side effects while in this study. Everyone taking part in the study will be watched carefully for any side effects. However, the Researcher may not know all the side effects or risks. Side effects may be mild or very serious. The Researchers may give you topical medications to help lessen side effects if you have any. Many side effects go away soon after you stop participating in the study. You should talk to the Researchers about any side effects that you have while taking part in the study.

There are risks and side effects related to the use of topical aminolevulinic acid (the chemical that becomes sensitive to blue light after it is applied to your face). These side effects include: Redness, pain, blisters, infection, increased sensitivity to sunlight, sunburns, darkening of your skin, and/or lightening of your skin.

There may also be risks to your privacy. The Researchers will store study records and other information about you in a secure location and will grant access only to those with a need to know on the research team. The photographs taken of you during this study will be uploaded to your electronic medical record. However, just like with other personal information kept by your health care providers, your banks, and others, even these safeguards cannot guarantee absolute protection of the data. If private information gets into the wrong hands, it can cause harm. Although rare, there are reported cases of breaches that have resulted in discrimination in insurance or employment.

For more information about risks and side effects, ask the Researcher.

You should not be or become pregnant or breastfeed while in this research study. The effects of ALA on the fetus during pregnancy and on infants via breast milk are unknown.

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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, half of your face will receive the standard photodynamic therapy treatment that is provided normally in the Dermatology clinic for precancerous lesions called actinic keratoses. This treatment has the potential to treat any actinic keratoses you may have.

We cannot promise any benefits to others from your taking part in this research. However, the information we get from this study may help us to develop better treatments for seborrheic dermatitis in the future.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the Institutional Review Board (IRB) and other University of California representatives responsible for the management or oversight of this study. The IRB is a group of people who monitor research here at the University

The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the study. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/compliance/pdf/notice.pdf) and in an attached document.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include: health issues that may necessitate treatment with antibiotics during the study period.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor

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or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury.

At the end of visit two, you will be paid $40 for completing visits one and two. If you do not follow up for visit two, we will not pay you. At the end of visit three, you will be paid an additional $20 for completing visit three. We will make the payments using gift cards.

Your images may be used for educational purposes, publications and/or presentations at conferences, and scientific meetings. There is no risk to taking photographs. Pictures will be used without using any identifying information or features.

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

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