Study Title: Early Molecular Changes in Vitiligo After Narrowband Ultraviolet Therapy

NCT No.: NCT03270241

04/21/2018

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Early Molecular Changes in Vitiligo After Narrowband Ultraviolet Therapy**

Application No.: **IRB00133884**

Principal Investigator: **PI: Dr. Noori Kim, MD**
Cutaneous Translational Research Program
Department of Dermatology
Johns Hopkins School of Medicine
601 North Caroline Street, Suite 8033
Baltimore, MD 21287
Tel: 410-502-7546
Fax: 410-955-5322

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.
- 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.

- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.
- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

2. Why is this research being done?

This research is being done to evaluate the molecular changes from NB-UVB in Vitiligo treatment and to identify potential targets for further study and for treating Vitiligo.

Vitiligo is a chronic skin disease of pigmentation that significantly affects patients' quality of life. Phototherapy is a clinically indicated, U.S. Food and Drug Administration (FDA)-approved treatment for vitiligo. Treatments are usually given in an outpatient setting about three times a week.

NB-UVB phototherapy has been demonstrated to be helpful in treating vitiligo in clinical studies, but few studies have shown how well phototherapy improves the quality of life for patients with vitiligo. The NB-UVB phototherapy device used in this study is one that is routinely used in our clinic as part of standard clinical care.

Adults, at least 18 years old, with vitiligo lesions who have no known history of adverse events or side effects to phototherapy may join.

How many people will be in this study?

Up to 20 people are expected to part in this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

You will be asked to take part in a screening visit and up to three NB-UVB treatment visits over the period of one week. Up to six 4mm punch biopsies will be obtained before treatment and up to one week after treatment at normal and affected skin sites.

Clinical Assessment:

We will review your medical history and a clinical examination will be done to assess your vitiligo and see if you are eligible to take part in this study.

NB-UVB Phototherapy Treatment:

The vitiligo lesions will receive three phototherapy treatments for up to one week period. The NB-UVB phototherapy treatment will start at 250 mJ/cm^2 at ascending dosage with each treatment, as outlined by standard NB-UVB phototherapy treatment. The dose of NB-UVB phototherapy will be modified if you have a skin reaction. This is part of standard care for using NB-UVB phototherapy.

All data collection is secured and stored in locked office of the principal investigator.

Before each treatment the study doctor will check your skin to assess side effects such as burning or redness. If needed, the phototherapy treatment will be modified as per routine clinical care guidelines. In addition, for any treatment interruptions, dosing will be adjusted according to recommendations used in standard of care.

At each visit, a thin layer of mineral oil will be applied to treated and non-treated skin patches as per the standard of care before phototherapy begins. The untreated parts of your body will be photo-protected in standard fashion (such as using a gown or sheet).

Clinical and safety assessments will be done for both treated and non-treated sites.

Questionnaires:
You will be asked to complete quality of life questionnaires at treatment visits. The aim of the questionnaires is to measure how much your skin problem has affected your life and your feelings towards your skin condition.

Photography:
We will take digital photograph of both treated and non-treated areas of your body at various time points throughout the study.

By signing this consent form, you acknowledge that these photographs may be used by Johns Hopkins for both educational and publication purposes. These photographs will be de-identified and coded with a number, but not your name.

Skin Biopsies:
A total of six punch biopsies from affected and normal skin regions at baseline and up to one week after completion of last treatment will be obtained. Biopsy sites will be determined by study doctors before the first biopsy. Biopsy sites will include vitiligo lesions that are large enough to be biopsied at 3 different locations within the lesion.

The amount of time taken for each biopsy is about 30 minutes. The biopsies will be done in the same way in which a clinical biopsy is done. We will inject a local skin numbing medicine. Then we will use a small punch biopsy instrument (about the size of a pencil eraser) to collect a piece of skin about 4 mm (1/4 inch) thick. Here is an illustration of the approximate size of the biopsy:

After we obtain the skin sample, each biopsy site will be closed with stitches to aid healing. The stitches will need to be removed one to two weeks after the biopsy. A scar is formed at each biopsy site, but generally heals well without complication.

You and your doctor will not get the results of these biopsies because they are being done for research. The results will not be useful for your medical care at this time.

Any remaining tissue material may be de-identified (without any information that could identify you) and stored for use in future research. Please see sub-section below.

Optional Storage of Samples for Future Research
As part of this study, we would like your permission to store some of your tissue samples collected in this study for use in future research about your skin condition. Any leftover tissue will be used anonymously (without any information that could identify you). More information about our use of your biospecimens can be found in this consent document under the heading *What happens to Data and Biospecimens that are collected in the study?*

Please initial your choice below:

_____YES, you may store and use some of my tissue samples collected in this study for future research about my skin condition.

_____NO, I do not want you to store or use any of my tissue samples collected in this study for future research about my skin condition.

Whether you check "Yes" or "No" will not keep you from taking part in this study.

Future Contact
We would like your permission to contact you about other studies that you may be eligible for in the future.

Please initial your choice below:

_____ YES, you may contact me in the future about other studies.

_____ NO, I do not want you to contact me about other studies.

How long will you be in the study?
You will be in this study for up to 2 weeks.

4. What are the risks or discomforts of the study?

Skin Biopsy:
You may have some redness and irritation of the biopsy sites. The biopsy will cause a small amount of pain, and there may be bleeding at the biopsy site. There is a very small chance of developing an infection. You will be left with a small scar that typically heals well and blends with the surrounding skin.

We will screen carefully for keloids (excess growth of scar tissue), but in rare individuals with no prior keloid history, keloids or excessive scarring may develop at the biopsy site. This risk is increased in people of certain ethnic backgrounds, which can be discussed with the study doctor.

Local anesthesia:
The risk associated with the use of local anesthesia (numbing medicine) is very small and is mainly related to minor discomfort (typically a burning sensation), possible bleeding, and a very small chance of infection.

Treatment with NB-UVB:
The reported side effects are: itching, burning, erythema (redness), desquamation (skin peeling), discoloration, blistering, ulceration, and dryness. There appears to be no increased risk for non-melanoma skin cancers or melanoma but all phototherapy modalities can induce photo-damage and photo-aging with prolonged use.

Mild side effects can be treated by the application of emollients such as petroleum jelly, increased severity of side effects may require discontinuation of the treatment, application of emollients or the application of topical corticosteroids.

As with all phototherapy devices, exposure to UV light, whether it is from the sun or from a device requires eye protection. Protective eyewear will be available in the office and the treatment unit.

Clinical evaluation:
There are no physical risks associated with the clinical evaluations or questionnaire procedures. We will perform full-body clinical evaluation of your skin and Vitiligo. We will evaluate your skin with Wood lamp in which the skin is examined while exposed to the black light emitted by Wood lamp. Black light is invisible to the naked eye because it is in the ultraviolet spectrum, with wavelength just shorter than the colour violet. The lamp glows violet in a dark environment, allowing visibility of nearly invisible de-pigmented vitiligo skin.

Confidentiality:
There is the risk that information about you may become known to people outside of this study. To protect against this, all samples will be labeled with a number, but not with your name.

There may be side effects and discomforts that are not yet known.

5. Are there risks related to pregnancy?

You cannot take part in this study if you are pregnant or planning to become pregnant.

While there are no medically documented associated risks to an embryo or fetus for phototherapy, there are few large clinical studies documenting the long term safety and effects of phototherapy during pregnancy.

For women who are capable of having children, we will require that you be on an acceptable form of contraception while receiving phototherapy.

6. Are there benefits to being in the study?

There may or may not be a direct benefit to you from being in this study. It is possible that treatment with NB-UVB phototherapy may improve your skin findings. This, however, cannot be guaranteed. If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

You can get the same NB-UVB phototherapy treatment without being in this study. You do not have to join this study to get treatment. If you decide not to join this study, other options are available. Other treatments include: topical corticosteroids (e.g. clobetasol or triamcinolone) or topical calcineurin inhibitors (tacrolimus or pimecrolimus).

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

Yes, you will be paid $30 for each biopsy obtained.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information they have already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that they have already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or

if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Noori Kim at 410-502-7546. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?
If you think you are injured or ill because of this study, call Dr. Noori Kim at 410-502-7546 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call the Dermatology Clinic at 410-955-5000. Ask to speak with the on-call dermatology resident.

d. What happens to Data and Biospecimens that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

16. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.