The University of Nottingham

Trust Logo

UK Dermatology Clinical Trials Network

HI-Light Vitiligo Trial

Home Interventions and Light therapy for the treatment of Vitiligo

You are invited to take part in our research study

- It is important you understand why the research is being done, and what would happen if you take part.
- If you have any questions about this information or this study, talk about it with others: your parents, the research nurse or your doctor.
- If you decide to take part, you can stop helping with the study at any time, and you won't need to tell us why. If you choose not to take part, this won't change anything about the quality of care you receive or will receive in the future for your vitiligo.
- Thank you for reading this information!

Important things that you need to know

- Small patches of vitiligo are usually treated with topical steroid ointments. Large areas of vitiligo are sometimes treated with light therapy (also known as NB-UVB), but patients have to visit hospital often for this therapy.
- There is not a lot of information about how well these two treatments work, and we don't know whether they would work together.
- Hand-held NB-UVB light units are available to use in the home on small patches of vitiligo. But, the NHS does not provide these for vitiligo patients at the moment. If this study shows that these lights work well and are safe, more patients may be given these lights as an NHS treatment.
- To find out which treatment works best, we will compare how the vitiligo changes in three different groups of participants:
    - Participants who use steroid ointment only
    - Participants who use light therapy at home only
    - Participants who use steroid ointment and home light therapy.
- When you join the study, you will have an appointment where we will ask questions about your vitiligo and how you are doing in general. You will have photographs taken of your vitiligo, and we will test how your skin reacts to ultraviolet light. You will need to come back the next day for us to read the results of the skin reaction test.
- After these two appointments, you will be sent ointment and a light to use at home for 9 months.
- If you take part, you will be asked to come back to clinic every 3 months for the first 9 months (5 appointments in total).
- Short questionnaires will then be sent to you to complete at home every 3 months for the following year (4 questionnaires in total). If you join the trial on or after 1st November 2016, your time left in the trial may less than less than be less than one year so you may complete fewer than 4 questionnaires.

Contents

How to contact us

If you have any questions about this study, at any time please contact your local research team at:

[Local trust contact details XXXXXXXXXXXXXXXXXXXXX]

NHS National Institute for Health Research

The HI-Light Vitiligo trial is funded by the National Institute for Health Research's HTA Programme (project number 12/24/02) to inform NHS care.

1. Why we are doing this study

Vitiligo causes loss of pigment (colour) on the skin and white patches appear. It affects around 1% of the population worldwide. There is not a lot of information about what treatments help vitiligo.

We have designed a study to test two commonly used treatments: topical steroid ointment and NB-UVB light therapy. We would like more information about how well these two treatments work, and would like to know how or if they work better when used together.

Light therapy is most commonly given at hospital on large vitiligo patches. We would like to see if light therapy at home could be an easy and safe treatment for patients with small patches of vitiligo.

Why it is importance to test different treatments on different groups of people:

To find out which treatment words best, we need to do a large study to compare steroid ointments to light therapy. To do this, participants will be in one of three treatment groups:
Group 1 will be using a steroid ointment
Group 2 will be using a home light therapy device
Group 3 will use both steroid ointment and the home light therapy unit

A computer will randomly split participants into the three groups, making sure that the same number of people is in each group. But, you won't know which group you are in because all groups will be given treatments which look the same:
Group 1 will have an ointment with steroid in it, but a dummy light (bulb that does not emit UVB light).
Group 2 will have a light which emits UVB rays, but a dummy ointment (with no steroid in it).
Group 3 will have both the ointment with steroid and the light with UVB rays.

The doctors, nurses, and trial staff will not know which group you are in either. We do this so that our ideas about what the results might be do not influence the actual results. Being able to compare the 3 groups fairly will help us best understand how each treatment works, and how they work together.

Every group will receive at least one treatment which may help vitiligo. No group is better than the other.

2. Why have I been invited to take part?

To help us answer our research questions, we are inviting 440 patients with vitiligo, like you, to help with the study.

We are looking for people who have at least one patch of vitiligo which has appeared or worsened over the past 12 months.

3. What will I have to do?

If you decide to take part you will need to come to **5 clinic visits** over a period of 9 months (2 initial appointments, and then one appointment every 3 months). The first 2 appointments will be to check your vitiligo, and the next 3 appointments will be to see if your vitiligo has changed since you started the treatments.

After you finish your 9 months of treatment, we will send you a questionnaire to fill in, at home, every 3 months for one year (**4 questionnaires** in total). If you join the trial on or after 1st November 2016, your time left in the trial may be less than one yearn so you may complete than 4 questionnaires.

What you will have to do during the Trial

1. **Telephone Screen (10 minutes):** A research nurse will explain the trial and will ask you a few questions about your vitiligo to see if you can take part.

2. **Joining the study (2 visits, 3 hours total):** To sign up, you will need to attend 2 hospital visits:

Hospital visit 1: A research nurse will tell you about the trial and answer your questions. If you want to take part, you will be asked to sign a form, called a consent form, to show you understand the study and are happy to join in. A dermatologist (skin doctor) will check your skin, and we will make sure you have the right type of vitiligo to take part. We will do a light test on your skin, called the Minimal Erythema Dose test (MED) to see how your skin reacts to ultraviolet light.

Hospital Visit 2: After your first hospital visit, you will need to come back to the hospital the next day. We will read your MED test results and will give you a treatment plan, which will tell you how long your light therapy sessions will be.

Other Activities that you will do at visit 1 or 2: We will ask you some questions about yourself and how you feel in general. You will have photographs taken of your

vitiligo and you and the nurse will choose up to 3 vitiligo patches to measure at your visits. (You will be able to treat as many vitiligo patches as you would like at home, but we will only check 3). You will also be trained on how to use your treatments. We will give you a training manual and a DVD to take home too.

More information about the MED test

An ultraviolet light B will be shone onto small patches of your skin, several times. This will take only a few minutes. The nurse will check those patches the next day because a small number of people can get a temporary rash after the test, meaning they should not have any light therapy treatment. The MED test is not painful, but some patches we test could become red and may take a while to go back to their normal colour. Even if you've had UVB treatment in before, we will still do the MED test because your skin's sensitivity to light can change.

3. At-home Treatments: After your second visit to the hospital, you will be sent a study pack to your home. This pack will contain your trial ointment and light therapy unit.

You should treat your vitiligo with both the ointment and light, for 9 months, following the instructions and treatment schedule the nurse gave you.

Your first light therapy session will probably last only a few seconds. In time, your skin will be more used to the light, and you will be able to use it for longer. The nurse will give you all the instructions you need to use the light safely and correctly.

We will also ask you to write down information about each treatment you do in a diary. You should bring this diary with you to all of your hospital visits.

4. Telephone call (10 minutes): Two weeks after your first appointment a member of our team will call you to make sure you have received your treatments in the post and you know how to use them.

5. Hospital visits 3, 4 and 5 (30 minutes each): Every three months you will be asked to come back to hospital. We will check your vitiligo patches, ask you how your treatment is going and see how happy you are with the treatment.

At the last visit we will take more photographs of your skin. This will take about 30 extra minutes.

6. Post-Treatment Questionnaires: After your last hospital visit, every 3 months for one year, we will send you a questionnaire to fill in at home. These questionnaires will ask you about your vitiligo patches, how you are feeling in general, and what you thought about the treatments and the trial.

There will be 4 questionnaires in total. The first 3 questionnaires should take about 10 minutes to complete, and the fourth, no longer than 20 minutes.

If you join the trial on or after 1st November 2016, your time left in the trial may be less than 1 year so you may completed fewer than 4 questionnaires.

To thank you for the time you are taking to help with the trial, we will give you a £10 gift vouchers at each hospital visit.

A few more things to know: If you agree to take part in this trial, we will write to your GP to explain you are taking part in the study. This is so your GP knows how your vitiligo treatment has changed.

Lastly, if you decide to take part, you can stop helping with the study at any time. You won't need to tell us why. Not joining in or stopping will not affect the standard of care you receive.

4. Possible disadvantages or risks?

NB-UVB Light therapy can cause dry skin, sunburn, cold sores or an itchy rash. You will be given advice on what to do if you have any side effects from using the light. Sometimes skin colour becomes darker than normal after UV light exposure; this may go quickly, or could take a bit longer to improve.

Patients who use light therapy for many years can have a higher risk of skin aging (Dryness, freckling, and wrinkling) or skin cancer. These risks are higher the longer you are exposed to UV light (including sunlight and treatment light). Because this study only lasts for 9 months, the amount of UV light exposure you have will be low, and not much more than you would normally get from the sun.

Topical steroid ointments may cause some stinging or burning at first; this usually gets better the more you use them. Using them for a long time can cause skin to lighten (which may be more noticeable with dark skin), look thinner or bruised, or for thread veins to appear. Other side effects could include spots, hair growth and spread of infection. In this study, the ointment is being applied every other week to make it less likely that these side effects will happen. **It is important to regularly check how your skin is doing during the trial.**

If you notice any side effects, you can let your research nurse know. They will give you advice on whether you should change you treatments to help any side effects. At the start of the study you will be given the telephone and email address of who to call if you experience side effects. Your skin will also be checked at each hospital visit for side effects. If you are unsure or have questions, you can contact your GP or dermatologist.

How other medications could affect light therapy: If you take any medication now, or start new medication during the trial, let your research nurse know! He/she will give you advice on if the medication is safe to use with the light therapy (some medications can make your skin more sensitive to light). Also, do not use any other light treatments during the trial: phototherapy, intense pulsed light treatment, laser treatments and sunbeds.

5. Possible benefits?

We cannot promise the study will help you. However, information we get from the study could help improve future care for patients with vitiligo.

6. What happens after the study?

After 9 months, you will be asked to return the light therapy unit and any ointment you have left. Future care for your vitiligo will be from your GP and/or a dermatologist as usual.

7. Will my taking part be kept confidential?

We will use ethical and legal guidelines to make sure we handle all information about you in confidence (not sharing it with anyone who isn't working on the study or who you haven't given us permission to share it with). If you join the study, some parts of your medical records and the data collected for the study will be looked at by the research team at the University of Nottingham. Some data may also be checked by authorised people to check that the study is being carried out correctly. Anyone who sees your data will be required to keep everything they see confidential and respect your right to privacy.

All information which is collected about you during the course of the research will be kept strictly confidential, stored in a secure and locked office, and on a password protected database. Any data about you which leaves the hospital will have your name removed (anonymised) and a unique code will be used instead so that you cannot be recognised.

Your contact details will be used by the trial coordinating centre (Nottingham Clinical Trials Unit) to send you your treatments by post. If you agree to it on the consent form, your details will also be kept after the end of the study so that we are able to contact you about the results of the study and future related studies. If you don't want your contact details to be kept and used in this way, or if in the future you decide you no longer want us to hold your personal details that is fine. You can let us know and we will remove your details from our database.

All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time, everyone involved in the study will make sure that your right to privacy is protected. Only members of the research team will have access to your data.

8. Results of the study

The results from this study will be published in medical journals, presented at medical conferences and shared with patient groups/relevant charities. We will send you a newsletter with a summary of the study findings, unless you ask us not to.

9. What if there is a problem?

If you have a concern or questions about any part of this study, you can speak to your research nurse or dermatologist working on the trial (their contact details are on the front page of this leaflet).

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure, via the Patient Advisory and Liaison Service (PALS) Insert local PALS details XXXXXXXXXXX.

If something goes wrong and you are harmed during the trial, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, you may have grounds to follow this up this legally, but may have to pay your own legal costs. The normal National Health Service complaints mechanisms will still be available to you.

10. Who has reviewed the study?

This study has been reviewed and approved by the Derby Research Ethics Committee (REC). The REC looks after the rights, wellbeing and dignity of people invited to take part in research studies. The study has also been reviewed by vitiligo patients.

Thank you for reading this leaflet