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 it would involve for you if you decide to take part.
- Please take time to read this information. Talk to others if you wish, and ask the research team if you would like more information.
- If you agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part, this will not affect your current or future treatment.
- Thank you for reading this information.

Important things that you need to know

- Small patches of vitiligo are usually treated with topical steroid ointments. Ultraviolet B light therapy (also known as NB-UVB) is also sometimes offered as a treatment, but it involves frequent visits to hospital and is mainly for large areas when vitiligo is more widespread.
- 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. However, these units are not available on the NHS. If we find that hand-held light therapy units at home work well and are safe, they may be accepted as a treatment option for vitiligo patients on the NHS.
- To help us understand more about these treatment options we are comparing changes in vitiligo 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 your child joins the study, you will have an appointment where we will ask questions about their vitiligo and how they are doing in general. Photographs will be taken of their vitiligo, and we will test how your child's skin reacts to ultraviolet light. You will need to come back the next day for us to read the results of your child's skin reaction test.
- After these two appointments, you and your child will be sent ointment and a light to use at home for 9 months.
- If your child takes 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 be less than 1 year so you may complete fewer than 4 questionnaires.

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How to contact us

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

Insert local trust contact details
XXXXXXXXXXXXXXXXXXXX

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 on the skin and white patches appear in the affected areas. This condition affects around 1% of the population worldwide. There is not a lot of information about what treatments work to 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 when vitiligo has spread. We would like to see if light therapy at home could offer a convenient and safe treatment for patients with small patches of vitiligo.

The importance of testing different treatments on different groups:

To answer these questions we need to conduct a large study, comparing steroids and 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

The decision as to which group your child will be allocated to will be done randomly by a computer and you will have an equal chance of being in one of the three groups. However, you will not know which group you have been assigned to, as all groups will apply an ointment and use a light: **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 participants have been assigned to either. We will not know which group each person was in until the very end of the trial. We do this so that expectations of 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.

Since we do not know if one treatment works better than the other, or if the two treatments together work better than one treatment on its own, there is *no advantage or disadvantage to being in one group over the other*. Every group will have one form of 'active' treatment that is routinely used to help in the management of vitiligo.

2. Why has my child been invited to take part?

To help us answer our research questions, we are inviting 440 patients with vitiligo, like your child, to help with the study. We are looking for children and adults 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 I take part?

If your child decides to take part in the trial, we will need to see them **5 times** in our clinics over a period of 9 months (2 initial appointments, and then one appointment every 3 months). The first appointments will be to assess your vitiligo and the follow-up appointments will be to see if and how your vitiligo is responding to the treatment. After your child finishes the 9 months of treatment, we will ask you to complete **4 questionnaires** at home, 1 every 3 months for one year. 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 complete fewer than 4 questionnaires.

What you and your child will have to do

1. **Telephone Screen (10 minutes):** A research nurse will explain the trial. You will be asked a few questions about your child's vitiligo to see if he/she is eligible.

2. **Joining the study (2 visits, 3 hours total):** To enrol in the trial, your child will need to attend 2 visits:

Hospital visit 1: You will be given information about the study and asked to give written consent if you and your child are happy to take part. A dermatologist (skin doctor) will check their skin, and we will ensure that your child is suitable to take part. We will do a light test your child's skin, called the Minimal Erythema Dose (MED) test to see how their skin reacts to ultraviolet light.

Hospital Visit 2: After the first visit, you and your child will need to come back to the hospital the following day. We will read your child's MED test results and tell you what your child's treatment plan will be.

Other Activities that you will do at visit 1 or 2: We will ask you some questions about you and your child, and how they feel in general. Your child will have photographs taken of your child's vitiligo and you and the nurse will choose up to 3 vitiligo patches to be assessed at your child's follow-up visits (Though you will be able to treat as many vitiligo patches as you would like at home). You and your child will also be trained on how to use the treatments, and given a training DVD to watch at home to remind you.

More information about the MED test

A number of doses of ultraviolet light B will be shone onto small squares on your child's skin. This takes only a few minutes and the result will be read the next day during hospital visit 2 to check for rare reactions of a short-lived rash which may mean they are not suitable for NB UVB light treatment. This test is not painful, but can create some areas of redness that may take a while to fade. Even if they have had UVB treatment in the past, the MED test will normally be required because skin's sensitivity to light can change.

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

You should treat your child's vitiligo with both the ointment and light, for 9 months, following the instructions and treatment schedule the nurse gave you. We will also ask you to record some information about each treatment in a diary, which you should bring with you to all of your child's hospital visits.

Your child's first light therapy session is likely to last only a few seconds. In time, their skin will be more tolerant of the light, and you will be able to treat it for a few minutes at a time. The nurse will give you all the instructions you need to do it safely and correctly. Please Remember: *Young children must not be left unsupervised when using the light*.

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

5. Hospital visits 3, 4 and 5 (30 minutes each): Every three months your child will be asked to come back to hospital. At this time we will review their vitiligo patches and ask you and your child how their treatment is going and how happy you are with it.

At the final visit we will take more photographs of your child's skin. This takes an additional 30 minutes.

6. Post-Treatment Questionnaires: We will send you a questionnaire to complete every 3 months after your last appointment, for a period of one year. These questionnaires will ask about your child's vitiligo patches, how they are feeling in general, and what you both 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 complete fewer than 4 questionnaires.

To acknowledge the time spent participating in the trial, we will give you an inconvenience allowance of £10, in gift vouchers, at each hospital visit.

A few more things to know: If you agree for your child to take part, we will write to their GP to explain they are taking part in the trial. This is so their GP knows about the change to their vitiligo treatment.

Lastly, you and your child are free to withdraw from the trial at any time, without giving a reason. This will not affect the standard of care your child receives.

4. Possible disadvantages or risks?

NB-UVB Light therapy can cause dry skin, a sunburn like reaction, cold sores or an itchy rash. You will be given advice on what to do if your child experiences side effects from using the light. Sometimes skin colour becomes darker than normal after UV light exposure; this may settle or persist for some time.

Premature aging of the skin (e.g. dryness, freckling, wrinkling) may occur in patients who have had UV light therapy for many years. They may also be at increased risk of developing skin cancer. The increased risk of skin cancer is related to the total lifetime UV exposure from sunlight as well as treatment. The duration of treatment in this study is only 9 months and so UV exposure above what your child would normally have from the sun is limited.

Topical steroids may cause some stinging or burning when they are first applied; this usually gets better as treatment is continued. They can also cause skin colour to lighten (which may be more noticeable with dark skin), thinning of the skin, thread veins or bruising if used regularly for long periods. Other possible side effects include acne-type spots, increased hair growth and spread of infection. In this

study, the ointment is being applied every other week to reduce the risk of potential side effects.

It is important to regularly check how your child's skin is reacting to treatment throughout the trial, as side effects may mean you need to adjust their treatments slightly. At the start of the study you will be given details of an appropriate person to contact if your child experiences treatment side effects. Your child will also be examined at the clinic visits for side effects. If in any doubt, contact your child's GP or dermatologist.

Potential interactions with other medications or light exposure: If your child is currently taking any medications, or start new medications during the trial, please inform the research nurse and he/she will provide advice. You child should also not use any other form of light therapy whilst in the trial; this includes any other kind of phototherapy, intense pulsed light treatment, laser treatments and sunbeds.

5. Possible benefits?

We cannot promise the study will help your child. 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 remaining ointment. Future care for your child's vitiligo will be provided by their GP and/or a dermatologist as usual.

7. Will my child's taking part be kept confidential?

We will follow ethical and legal practice and all information about your child will be handled in confidence. If your child joins the study, some parts of their medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to your child as a research participant and we will do our best to meet this duty.

All information which is collected about your child 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 your child which leaves the hospital will have their name removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your contact details will be used by the trial coordinating centre (Nottingham Clinical Trials Unit) to send your child's treatments by post. If you consent to it, they will also be kept after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). You can ask us to remove this personal information later if you change your mind. All other data (research data) will be kept securely for 7 years. After this time your child's data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your child's confidentiality; only members of the research team will have access to your personal data.

8. Results of the study

Findings from this study will be published in medical journals, presented at medical conferences and made available to 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 aspect of this study you should ask to speak to the local researchers (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.

In the event that something does go wrong and your child is harmed during the study, there are no special compensation arrangements. If your child is harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you and your child.

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