

The HI-Light Vitiligo Trial:

This leaflet tells you about a study being conducted across the UK to assess how well two different treatments used at home work to improve the appearance of vitiligo.

1. Why are we doing this study?

- Vitiligo causes loss of pigment in the skin and white patches appear in the affected areas.
- There is not a lot of information about effective treatments for vitiligo.
- Small patches of vitiligo are usually treated with steroid ointment. Going to hospital for light therapy is also sometimes offered as a treatment when vitiligo is more widespread.
- Though these treatments are commonly used, we do not know how well these two treatments work, and we don't know whether they work together.
- Hand-held light therapy units, used to treat small patches of vitiligo are not available on the NHS. If we find that hand-held light devices used at home work well, they could become one of the treatment options available on the NHS for vitiligo patients.
- We have designed a study to test two commonly used treatments: 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.

2. Why have I been invited to take part?

We are inviting 440 children and adults with vitiligo, like you, to help with this trial.

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

3. What will I have to do if I take part?

All participants who agree to take part will use a combination of steroid ointment and light therapy, at home, for a period of 9 months.

All patients will receive an ointment and a hand-held light emitting device. These will either be:

- A steroid ointment and a dummy light (bulb that does not emit UVB light)
- A dummy ointment (ointment with no steroid in it) and light which emits delivering ultraviolet light to the skin
- A steroid ointment and a device delivering ultraviolet light to the skin

You will be assigned randomly to a group (like tossing a coin). You will not know which treatments you have been given, and the nurses and doctors won't know either. This is so that later in the study, when we ask how well the treatments worked, the response is not influenced by knowing what treatments you were using. This will help us to make a fair decision about which treatments work best.

On top of doing your at-home treatments, we will

need to see you **5 times** in our clinics over a period of 9 months (2 initial appointments, and then one appointment every 3 months).

Hospital visits 1 and 2

The first two appointments will be to assess your vitiligo and make sure you are eligible to take part.

You will have a light test done on your skin, called the minimal erythema dose (MED) test, to see how your skin reacts to ultraviolet light, and photographs will be taken of some of your vitiligo patches. You will also be trained how to apply the ointment and use the light therapy unit.

These two appointments would need to be one day apart from each other. You could expect to be at the hospital for 3 hours in total, spread across the two days.

Hospital Visits 3, 4 and 5

The follow-up appointments will be to see if and how your vitiligo is responding to the treatments.

These appointments would be about 30 minutes each. The 5th appointment would be slightly longer, as we will take photographs of your skin again, to compare how your skin was before the treatment to how it is after the treatment.

At home treatments

For a period of 9 months you will be asked to do

the following treatments at home:

- Light therapy session, every other day (3-4 times per week)



- Apply ointment, every day, every other week (one week on, one week off)

Follow up questionnaires

After you finish your 9 months of treatment, we will ask you to complete **4 questionnaires** at home, 1 every 3 months for one year.

The first three questionnaires should take 5-10 minutes each. The last questionnaire will take slightly longer, as we will also ask you your thoughts about the treatments and the trial.

It total, you will be helping us with the study for 21 months.

4. Will my taking part be kept confidential?

Yes. All of the information that is collected about you during the study will be kept strictly confidential and will be held securely.

5. Who has reviewed the study?

This study has been 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 the University of Nottingham, the National Institute of Health Research Health Technology Assessment Programme (trial funders), and a panel of patients with vitiligo.

The study is being coordinated by Nottingham Clinical Trials Unit at the University of Nottingham.

How can I find out more?

If you are interested in taking part, or would like more information:

- Visit the website:
www.hilightstudy.com
- Send us an email:
hilight@nottingham.ac.uk
- Contact the Research Team
Tel: 0115 884 4937



Home Interventions and Light therapy for the treatment of vitiligo

Summary Information leaflet