

The HI-Light Vitiligo Trial

An Information Sheet for children aged 11 to 15



Why is this study important?

If areas of your skin lose pigment (colour), and are whiter than the rest of the skin, you may have vitiligo. Although this skin disorder is fairly common, we still do not fully understand the causes.

At the moment, we don't have a cure for vitiligo, and there is not a lot of information about what can make it better. Doctors sometimes prescribe creams or ointments (like creams, but more oily), or light therapy (shining special light on the skin) in hospital. But, we don't know which is best.



What would we like to know?

We would like to compare using light therapy at home with using steroid ointments (ointment with medicine in it) to see if either treatment works or if one works better than the other. Or maybe using both the light and the ointment together will give the best result. We do not know.



Why have I been asked to help?

To find out which treatments are the best for vitiligo, we need 440 people with vitiligo including adults and children, like you, to take part in our study.

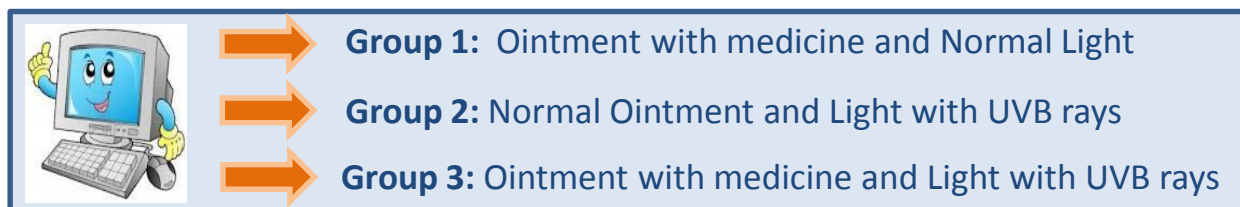


How will we find out which is the best treatment?

To find out which treatment works best, we will give everyone who helps us in the trial a tube of cream and a light to use at home:

- The cream you get to put on your skin will be either be a normal ointment, or an ointment with medicine in it.
- The light you get to shine on your skin will either be a normal light, or a light that shines rays, called UVB rays.

To decide what type of ointment and light everyone will get, a computer will split everyone who signs up to the trial into 3 groups, making sure that the same number of people are in each group:



We will compare these three groups at the end of the trial, to see if one of the treatments works best for vitiligo. Every group will receive at least one treatment which may help vitiligo. So, no group is better than the other.

You won't know which group you are in, and the doctor and nurse won't know either. We keep the groups a secret so that we can be sure that the information we find out about the different treatments is fair. We need to have three different groups so that we can compare how well each treatment works fairly.

Every group is really important to help us understand how to help people with vitiligo.



What will I have to do if I help?

If you decide to help us, you will visit us at hospital **5 times** over a period of 9 months:

1. **Visit 1, Day 1:** When you first start the trial, you will talk about the study with a nurse who will make sure you understand the study and are happy to help. A skin doctor will check your skin, and you will have photographs taken of the white patches on your skin. The nurse will also ask you and your parent/guardian questions about you and your vitiligo and do a special light test on your skin. This test is called Minimal Erythema Dose test (MED). A special light will be shone on to small areas of your skin to see how your skin reacts to ultraviolet light.
2. **Visit 2, Day 2:** You will come back to hospital the next day for the nurse read your MED test results. These results will tell the nurse how long you should start using the light unit for.
3. **Visit 3, 3 months later:** The nurse will check your skin and how your treatment is going.
4. **Visit 4, 6 months later:** This visit will be exactly the same as the one before.
5. **Visit 5, 9 months later:** This visit will be the same as visit 3 and visit 4, but we will ask you and your parent/guardian a few more questions, and also take more pictures of your skin.



How will I use the treatments at home?

You'll be sent ointment and a light at home (Remember, you won't know which group you are in!)



This is what the light will look like!

Your parent or carer will help you use the ointment and the light on your skin at home for 9 months. When you first visit the hospital the nurse will show you how to put the ointment on your skin and how to use the light at home. You will get a DVD with these instructions to remind you.

You will get a diary to write down how you use the ointment and the light every time you use it.



What will I do after I finish the treatments?

After you see the nurse at Visit 5, your treatment will be finished. You will give the light and any ointment you haven't used back. We will still need a bit more information from you though!

We will send you some questions to answer either online or in the post. You will get the questions sent to you **4 times**: once every 3 months for a year after your last visit to the nurse. You can fill these questions in with your parent/guardian, and they will ask you about your vitiligo patches, how you feel in general, and what you thought about the treatment and the trial. If you join the study on or after 1st November 2016, your time left in the study may not be a year and so you may have less questionnaires sent to you.

All of the information you will help us to gather is important: It will help us to see whether any of the treatments work better than the others. It's also really important to know if none of them work very well: we will then try to think of new ways to help improve the appearance of vitiligo.



Is there anything else I should know?

It is up to you to help with this study. If you decide to help now, but change your mind later, that is fine too. You can stop the trial at any time.

Any information we collect about you will stay *confidential*: this means, we will not share it with anybody who isn't working on the study. The information we collect, called data, is also kept *anonymous*: this means that we use a special code to label it, and we do not use your name.

If you have any questions, you can ask your parent/guardian, the research nurse, or the doctor!

Thank you for reading this information!