

Your 9 month visit

Here are a few things to remember about your last visit with the nurse at 9 months:

- **BEFORE** your visit - please **STOP using trial treatments for 2 days before your 9 month appointment**. This will allow for any redness to settle down before the nurse sees you.
- Remember to take your light device with you to clinic.
- Remember to take any unused ointment with you to clinic.

Don't forget, we will be sending questionnaires every three months for a year after your final clinic appointment.

If you are happy to receive the questionnaires via email to complete online, but have not yet provided your research nurse with an email address, then please do so.



Emails will be sent from ctu@nottingham.ac.uk

Keep in touch!



Please be sure to get in touch with your local research team or the central coordinating centre if either your address or contact telephone number has changed recently.

Or for any general queries please get in touch with the study coordinating team at Nottingham Clinical Trials Unit:

Study Manager - Garry Meakin

Study Coordinator - Jen White

✉ highlight@nottingham.ac.uk

☎ 0115 823 1586



Participant Newsletter - June 2016

Thank you so much for your continued participation in the HI-Light Vitiligo Trial.

You are helping us answer a very important question about the treatment of vitiligo.

The HI-Light study is currently one of the largest studies in vitiligo and in April this year we hit our half way target when the 220th participant joined the study.

Thank you very much for making this commitment and agreeing to take part in our research.

Trial by numbers

- * 265 people have joined the study to date, that's 60% of our overall target of 440 participants
- * 16 NHS Trusts are involved in the study throughout England, Wales and Scotland
- * 25% of participants in the study are children



Please keep this newsletter alongside your HI-Light trial treatment package as it contains important information that you may need to refer to in the future!

Important!

Things you need to know

Did you know? It may take a while for your vitiligo to respond to treatment and in some cases may even appear to get worse before it gets better. We are looking at how noticeable the vitiligo will be at the end of the 9 month treatment period.

Did you know? If you are thinking about going on holiday you can take your light device and ointment with you. If you are traveling abroad don't forget to take a plug adapter. If however you are going away and do not wish to take your study treatments with you, please ensure that this is noted in your diary.

Did you know? If you miss 4 or more treatment sessions please contact your local research team who will advise you further on how to proceed.

Side effects - your safety guide

Side Effect	What to do?
Itchy or Dry Skin	Apply moisturiser 3-4 times a day. Do NOT apply moisturiser in the 2 hours before light treatment as this can act like a sunscreen and stop the treatment from working. You can continue treatment as normal.
Tan around edges	This is normal. You can continue treatment as normal.
Rash	Stop the treatment immediately. Call your research team. If out of hours and the rash is causing significant symptoms, seek medical assistance.
Cold Sore	Stop light treatment until the cold sore has healed. Call the local research team to decide what dose to restart your light treatment at.

If you suspect that you are experiencing any of the below side effects, please ensure that you record them in the 'Other side effect log' in your handbook. It is important that you **contact a member of the research team for advice. You should not wait until your next clinic visit.**

- ⇒ Skin thinning
- ⇒ Bruising
- ⇒ Stretch marks
- ⇒ Spidery blood vessels in the skin
- ⇒ Acne-type spots
- ⇒ Excess hair growth

Please follow the below guidance if you experience any redness (also found on page 7 of your handbook)

- ⇒ Grade 1 Erythema (redness) - your skin is red but not hot or painful. The redness has lasted no more than 1 day. **For your next treatment go back one step.**
- ⇒ Grade 2 Erythema (redness) - your skin is not hot, but may be slightly uncomfortable. This redness may last for more than 1 day. **Skip your next treatment go back one step. Do not use the light if your skin is still red.**
- ⇒ Grade 3 or 4 Erythema (redness) - your skin is hot and painful and you may have blisters on the red patches of your skin. Grade 3 erythema will last about 3 days and grade 4 erythema can last 4/5 days. **STOP YOUR LIGHT TREATMENT and apply a thick layer of your trial ointment. Contact your local research team and do not restart treatment until you have been advised by the team.** If this happens on a weekend or out of hours call your local hospital and ask to speak to the on-call dermatologist or attend your local emergency department.

Remember—If you are unsure about anything at all, please contact a member of your research team who will be happy to assist!