HI-Light
Vitiligo Trial

Participant Newsletter - Results Edition

# The HI-light Vitiligo Trial

## Results of the UK DCTN HI-Light Vitiligo Trial

**The HI-Light Vitiligo Trial recruited 517 adults and children across the UK, making it one of the largest trials of its kind in the world. We have now finished analysing the data and are pleased to share the results with you.**

### Why was a trial needed?

Vitiligo causes loss of pigment in the skin and affects around 1% of the population worldwide. Vitiligo can have considerable impact on ones quality of life and sense of wellbeing.

Vitiligo affecting the hands and arms

There is no known cure for vitiligo; currently available treatments include full body UVB light therapy and steroid ointments. However, full body UVB light therapy involves frequent visits to hospital and is not suitable for smaller or isolated patches of vitiligo. Whilst steroid ointments and UVB light therapy are mainstream standard vitiligo treatments, there is limited evidence available about how well they work or whether they may work better when used together for treating vitiligo.

The NIHR (National Institute for Health Research—the research arm of the NHS) funded this trial to compare how safe and effective steroid ointments and handheld home UVB light therapy are for treating small patches of vitiligo.

### What did we do?

When you signed up to the trial you received an ointment and a handheld light-emitting device which were either:

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

*The steroid ointment used in the trial was mometasone furoate 0.1% ointment and the UVB light devices were Dermfix 1000 MX units supplied by Androv Medical.* You were randomly assigned (like tossing a coin) to one of the these groups, and neither you nor the nurses or doctors knew which treatments you had been given. We asked you to apply the ointment every day for one week on, and one week off, and to use the light device every other day for 9 months.

On top of doing your at-home treatments, we saw you for 3 clinic visits (3, 6 and 9 months after starting treatments), and sent you questionnaires at 12, 15, 18 and 21 months after starting treatment. At your appointments and through the questionnaires we tracked changes on up to three patches of vitiligo, including how noticeable you thought each patch was to see if using these treatments were an effective way of treating vitiligo.

University of Nottingham
UK | CHINA | MALAYSIA

UK Dermatology Clinical Trials Network

NOTTINGHAM CLINICAL TRIALS UNIT

## What did the results show?

The HI-Light Vitiligo trial aimed to find out whether treating vitiligo with a handheld UVB light, or with the light and a steroid ointment was better than treatment with a steroid ointment on its own.

We asked participants to judge how noticeable their target vitiligo patch was after 9 months of treatment.

**We considered the treatment was a success if the participant response was that their patch was 'a lot less' or 'no longer' noticeable at the 9 months.**

**The results showed that using both treatments together was better than using just steroid ointment or UVB light on their own and combination treatment was likely to achieve a treatment response more quickly.**

Patches on the hand and feet were less likely to respond well to treatment than other parts of the body.

Almost two thirds of people using both treatments in combination achieved at least partial treatment response by 9 months (27% said their vitiligo was no longer noticeable or a lot less noticeable, and 35% said their vitiligo was slightly less noticeable). Using steroid ointment alone was also a useful treatment for some participants and is likely to remain the first treatment recommended for use (17% said their vitiligo was no longer noticeable or a lot less noticeable, and 24% said their vitiligo was slightly less noticeable).

People who used the treatment more often were more likely to have a successful treatment response.

We also wanted to find out if any improvement in the vitiligo patches was maintained once the 9 month treatment phase stopped. Unfortunately, we did not collect as many questionnaires as we would have liked, but from the data that was returned we learned that the improvements in the vitiligo patches faded over time (between 3 and 9 months after stopping treatment). It is possible that ongoing treatment is needed to maintain the improvements in the vitiligo.

The trial also showed that these treatments are safe to use at home for up to 9 months with minimal side effects.

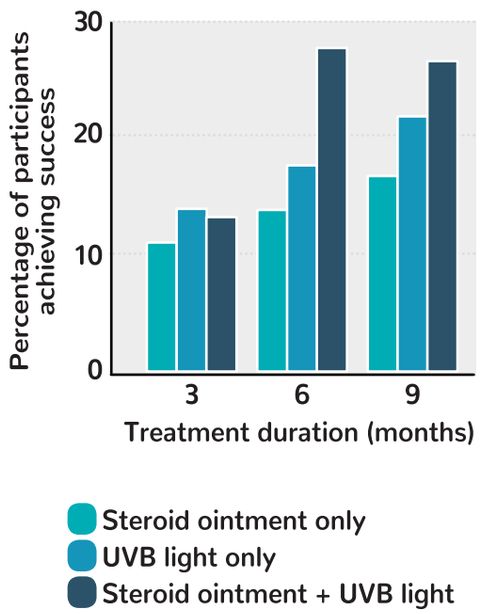


Figure 1:
Graph showing the percentage of trial participants with treatment success at the target patch during the treatment part of the trial.

## Conclusion

This trial showed that using steroid ointment and UVB light together is likely to be better than steroid creams used alone, although for some people steroid creams alone can be effective and remains a useful treatment. If the treatments are to work, they need to be followed closely, and requires a significant time commitment over many months.

Further research is needed to find the best way of maintaining any improvements to the vitiligo over the long term. With no known cure for vitiligo, and very few treatment options available, combination treatment with steroid ointment and handheld UVB light provides an alternative treatment option for people with small areas of vitiligo. Further work is needed to explore how best to make home UVB light treatment available within the NHS, as this service is not currently offered as normal care in most UK hospitals.

If people with vitiligo wish to purchase their own device for home treatment, we would recommend seeking expert clinical advice prior to using the light treatment.

## Being part of the HI-Light trial

**At the end of the trial we interviewed 25 trial participants (children, parents and adults) about their experience of taking part in the research and using the treatments.** We used the information from these interviews to help us understand the results from the trial and to develop our recommendations about how these treatments might be used by doctors in the future. **We found out that on the whole participants:**

- Had realistic expectations. Most people did not expect their vitiligo would go away completely.
- Understood how to use the treatments. They said the nurses gave thorough training and the participant handbook was very important.
- Used treatments correctly. But some didn't always use the light because of how long it took, side effects, life events (e.g. holiday) and feeling like it wasn't working.
- Were able to notice a change in vitiligo at 9 months with the help of photographs.

## What will happen to the results now?

**Although the trial has ended and we know the result, we haven't finished working on the trial yet.**

As this is one of the largest vitiligo trials that has ever been completed; the results of this trial will be shared with **vitiligo patients, doctors, researchers and people who make decisions about which treatments get funded on the NHS.** We hope that this trial can help us all make better informed decisions about how to treat vitiligo.

HI-light results reveal meeting

**We are working on publishing the results in medical journals, and sharing them at conferences across the UK and internationally. We are also working with dermatology networks and vitiligo charities to ensure the trial results are as widely shared as possible.**

## Who conducted the Trial?

Dr Jonathan Batchelor

Prof Kim Thomas

The trial was led jointly by Dr Jonathan Batchelor (clinical lead) and Professor Kim Thomas (academic lead), based at the Centre of Evidence Based Dermatology and coordinated by Nottingham Clinical Trials Unit, both within the University of Nottingham's School of Medicine.

The UK Dermatology Clinical Trials Network (UK DCTN) supported the development of the trial, and clinicians, nurses and CRN nurses, researchers and patient representatives from across the UK were involved in designing and conducting the study.

The trial was funded through a research grant by the National Institute for Health Research (NIHR), the research arm of the National Health Service (NHS).

## Further information

We hope you found the results of the trial interesting. If you'd like more detailed information about the trial and its results, links to any articles we publish about this research can be found here, in due course:

**vitiligostudy.org.uk**

**We would like to take this opportunity to *thank you* for being involved in the HI-light trial and giving up your time to attend clinic visits and complete questionnaires. Your enthusiasm and willingness to take part in research made the trial possible.**

*Thank you from the whole HI-Light team!*

FUNDED BY
NIHR | National Institute for Health Research

This newsletter presents independent research funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme (project number 12/24/02). The views and opinions expressed in this article are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, the National Health Service or the Department of Health and Social Care.