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Home interventions and light therapy for the treatment of vitiligo

Submission date
08/01/2015

Recruitment status
No longer recruiting

Registration date
08/01/2015

Overall study status
Completed

Last Edited
09/02/2023

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Vitiligo is a common skin disorder affecting about 1% of the world's population, regardless of age, sex or skin colour. Vitiligo causes white patches on the skin, which can spread to cover large areas of the body. It is more noticeable on dark or tanned skin, causing people with vitiligo to be stigmatised in some communities. Vitiligo can cause feelings of panic, depression and despair. Although vitiligo is not fatal, it can have a devastating effect on the quality of life of those who have it, particularly if it affects visible sites such as the face and hands. Children can experience teasing and bullying as a result of having the disease and many adults report a lack of confidence, poor self-esteem and an inability to form relationships. Current treatments for vitiligo are limited. They seldom restore natural skin colour to all the white patches and do not prevent the disease from coming back. In the early stages of the disease the use of corticosteroid creams or other ointments can sometimes be successful. GPs are often unaware of the psycho-social effects of vitiligo and in the absence of treatments specifically licensed for vitiligo may offer no help to the patient apart from special make-up to cover up the white patches. Light treatment prescribed for extensive vitiligo can work for some, but requires prolonged and frequent visits to hospital. 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. There is not a lot of information about how well steroid creams and light therapy work to improve the appearance of vitiligo, and we do not know whether they would work, or work better, together. The aim of this study is to find out more information about how well the treatments work, and to find out if they work, or work better, when used together.

Who can participate?
Children aged 5 years and over and adults with active vitiligo (new or spreading patches) that affects less than 10% of their body

What does the study involve?
Participants are randomly allocated to receive either light therapy plus a placebo (dummy) ointment, or a steroid ointment plus placebo (dummy) light therapy, or a combination of steroid ointment and light therapy. The light therapy is delivered using a small hand held light therapy device used three times a week, and the ointment is applied to the skin once daily on a 'one week on, one week off' basis. The light therapy device is easy to use and has a spacer to avoid

the light getting too close to the skin. There are also safety goggles to protect the eyes from the light. The participants are interviewed beforehand, given a leaflet to explain the study, and are shown a training video on how to use the treatments. They are asked to use a diary to record their treatment sessions and any side effects. They are supervised by a research nurse, and are able to contact the study team should there be any problems with the treatment. Participants receive treatment for 9 months and their response to treatment is assessed in clinic every 3 months. At the end of the treatment period participants are followed-up for a further 12 months so that the long-term response to treatment can be checked.

What are the possible benefits and risks of participating?
This study could add to the choice of treatments available for people with vitiligo, many of whom receive no treatment at all. Should the study prove to be a success, it could make a big difference to the lives of many people who have not had much help for what has often been considered a trivial, cosmetic condition. By giving people with vitiligo the opportunity to treat themselves or their children at home, participants avoid the inconvenience of having to attend hospital two or three times a week for light therapy. There is also the possibility that early treatment of small vitiligo areas could mean shorter treatment periods and better treatment response. The burden of participation in the study is low and the risks are small. Both of the compared treatments are recommended for the treatment of vitiligo and are appropriate for both children and adults. One possible side effect of the light therapy is burns, but clear instructions as to how to distinguish burns from just a reddening of the skin will be given and treatment can be adjusted accordingly.

Where is the study run from?
The study takes place in about 16 hospitals in the UK, and is co-ordinated from the Nottingham Clinical Trials Unit in collaboration with the Centre of Evidence Based Dermatology.

When is the study starting and how long is it expected to run for?
May 2015 to October 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Rachel Haines

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2014-003473-42

Protocol serial number
17720; HTA 12/24/02

Study information

Scientific Title
Home interventions and light therapy for the treatment of vitiligo

Acronym
HI-Light Vitiligo

Study objectives
The HI-Light trial has been designed to test two commonly used treatments: topical steroid ointment and NB-UVB light therapy. The trial aims to find out more information about how well the treatments work, and to find out if they work, or work better, when used together.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/122402
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/130657/PRO-12-24-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/EM/1173; First MREC approval date 27/10/2014

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vitiligo

Interventions
Participants will be asked to treat their vitiligo patches at home for a period of 9 months. Participants will be allocated to three groups:
1. NB-UVB light therapy (Dermfix Model 1000MX) plus placebo ointment (white soft paraffin)

2. Placebo NB-UVB light therapy (Dermfix 1000MX with no NB-UVB output) plus potent topical corticosteroid ointment (Mometasone Furoate 0.1% [Elocon])
3. NB-UVB light therapy (Dermfix Model 1000MX) plus potent topical corticosteroid ointment (Mometasone Furoate 0.1% [Elocon])

Intervention Type
Mixed

Primary outcome(s)
Patient-reported treatment success based on vitiligo noticeability scale at target lesion; Timepoint(s): 9 months

Key secondary outcome(s))
Current secondary outcome measures as of 24/07/2019:
1. Adverse events and adverse device effects; Timepoint(s): 3, 6, 9 months.
2. Cost-effectiveness; Timepoint(s): 21 months.
3. Investigator assessed onset of treatment response (including cessation of spread); Timepoint (s): 3, 6, 9 months.
4. Investigator assessed percentage of repigmentation; Timepoint(s): 3, 6, 9 months. Assessed by digital image at 9 months.
5. Patient reported Maintenance of Repigmentation (3 lesions); Timepoint(s): 12, 15, 18 ,21 months.
6. Patient reported treatment success based on vitiligo noticeability scale at three body sites; Timepoint(s): 3, 6, 9 months.
7. Quality of Life measures; Timepoint(s): 9 and 21 months.
8. VNS treatment success by blinded review of digital images at 9 months.

Previous secondary outcome measures:
1. Adverse events and adverse device effects; Timepoint(s): 3, 6, 9 months
2. Cost-effectiveness; Timepoint(s): 21 months
3. Investigator assessed onset of treatment response (including cessation of spread); Timepoint (s): 3, 6, 9 months
4. Investigator assessed percentage of repigmentation; Timepoint(s): 3, 6, 9 months
5. Reassessed by digital image at 9 months
6. Patient reported Maintenance of Repigmentation (3 lesions); Timepoint(s): 12, 15, 18 ,21 months
7. Patient reported treatment success based on vitiligo noticeability scale at three body sites; Timepoint(s): 3, 6, 9 months
8. Quality of Life measures; Timepoint(s): 9 and 21 months

Completion date
01/07/2019

Eligibility

Key inclusion criteria
1. Patients 5 years of age or over with a diagnosis of non-segmental vitiligo confirmed by a dermatologist
2. Vitiligo limited to less than 10% of body surface area, with at least one patch that is reported by the participant to have been active (new onset or spread) in the last 12 months
3. No other active therapy for vitiligo (or willing to stop current treatment – no washout period

required)
4. Able to administer the intervention safely at home
5. Able and willing to give informed consent (or parental/guardian consent in the case of children)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
517

Key exclusion criteria
1. Other types of vitiligo (e.g. segmental or universal vitiligo)
2. Patients with vitiligo limited to areas of the body for which NB-UVB
light therapy or potent topical corticosteroids would be inappropriate (e.g. around the genitals)
3. History of skin cancer (ever)
4. History of radiotherapy use (ever)
5. Photosensitivity (e.g. lupus, polymorphic light eruption, solar urticaria, chronic actinic dermatitis, actinic prurigo, porphyria or other photosensitivity disorders e.g. dermatomyositis)
6. Pregnant, breastfeeding or likely to become pregnant during the 9-month treatment period
7. Current use of immunosuppressive drugs (e.g. e.g. ciclosporin, azathioprine, mycophenolate mofetil, methotrexate, systemic tacrolimus)
8. Allergy or contraindication to mometasone furoate or any of its components (e.g any cutaneous bacterial, viral or fungal infections in the area to be exposed to trial treatments), as listed in section 4.3 of the SmPC
9. Current participation in another clinical trial or intervention study

Date of first enrolment
01/05/2015

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham Clinical Trials Unit
Nottingham Health Science Partners
Room 2201
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Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets analysed during the current study will be available upon request from the NCTU (ctu@nottingham.ac.uk), a minimum of 6 months after publication of the main results paper. Access to the data will be subject to review of a data sharing and use request by a committee including the CI and sponsor, and will only be granted upon receipt of a data sharing and use agreement. Any data shared will be pseudoanonymised which may impact on the reproducilbilty of published analyses.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	30/11/2020	Yes	No
Results article		28/12/2020	09/02/2023	Yes	No
Protocol article	protocol	03/04/2018		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	QA and characterisation of home UV devices	01/10/2020	28/10/2020	Yes	No
Other publications	Economic evaluation	04/11/2020	09/02/2023	Yes	No
Other publications	Nested process evaluation	30/05/2022	09/02/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes