ISRCTN18213910 https://doi.org/10.1186/ISRCTN18213910

Study comparing localised hand psoralen immersion combined with ultraviolet A (PUVA) with localised hand narrowband ultraviolet B (UVB) for the treatment of hand eczema

Submission date
27/04/2012

Recruitment status
No longer recruiting

Registration date
27/04/2012

Overall study status
Completed

Last Edited
26/08/2016

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to compare two types of phototherapy (light therapy) for patients with hand eczema. PUVA treatment (psoralen immersion combined with UVA light) is often used for eczema that does not respond to topical treatments. However, PUVA has disadvantages and an alternative treatment is narrow band UVB light treatment (NB UVB), which has been effectively used for whole body eczema. This study aims to provide data to plan a definitive trial of PUVA versus NB UVB for treatment of hand eczema.

Who can participate?
Patients with any type of hand eczema affecting the palmar skin who have been referred for PUVA.

What does the study involve?
Participants will attend phototherapy sessions twice per week for a maximum of 14 weeks. Participants will be randomly allocated to one of two groups. Group 1 will receive NB UVB phototherapy to the hands (i.e., their hands will be exposed to UVB light). Group 2 will receive PUVA phototherapy to the hands (i.e., their hands will be soaked in a diluted solution of psoralen and then exposed to UVA light).

What are the possible benefits and risks of participating?
Possible benefits include improvement of symptoms. There are no known risks of participating in the study.

Where is the study run from?
The Newcastle upon Tyne Hospitals NHS Foundation Trust Royal Victoria Infirmary (UK).

When is the study starting and how long is it expected to run for?
The study is due to commence in August 2012. Recruitment will last for 15 months.

Who is funding the study?
NIHR Research for Patient Benefit.

Who is the main contact?
Claire Oyston (Trial Manager)
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11799

Study information

Scientific Title
Observer blind randomised controlled pilot study comparing localised hand PUVA with localised hand narrowband UVB for the treatment of hand eczema

Study objectives
This study aims to compare two types of phototherapy for patients with hand eczema. Some previous research has suggested that narrow band UVB light treatment may be as effective for hand eczema as PUVA. Therefore this pilot study will assess the feasibility and refine the methodology for a large multicentre study of PUVA vs narrowband UVB for the treatment of hand eczema. Specifically we will look at the recruitment, retention and response rates of patients. Also test the integrity of the study protocol and pilot the collection of the primary and secondary outcome measures.

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=11799

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee North East Sunderland, 4 April 2012,ref: 12/NE/0033

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Skin; Subtopic: Skin (all Subtopics); Disease: Dermatology

Interventions
76 participants will be randomised to two groups:

Group 1 will receive narrow band UVB phototherapy to the hands. Hands will be exposed to UVB light.

Group 2 will receive PUVA phototherapy to the hands. Hands will be soaked in a diluted solution of Psoralen and the exposed to UVA light.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The proportion of patients responding (clear or almost clear PGA score) Timepoint(s): 12 weeks

Secondary outcome measures

1. The percentage improvement in the Modified Total Lesion Symptom Score (mTLSS)
2. Dermatology Life Quality Index (DLQI))
3. Health economic evaluation

Overall study start date
01/08/2012

Completion date
28/06/2013

Eligibility

Key inclusion criteria
1. Patient has provided written informed consent for participation in the study prior to any study specific procedures
2. Palmar eczema not responding to topical treatments
3. Over 18 years of age
4. No topical treatments (except emollients for 48 hours)
5. No systemic treatments for eczema treatment for 3 months
6. Absence of clinical evidence of bacterial, fungal or viral infection
7. Not pregnant
8. Target Gender: Male & Female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 76; UK Sample Size: 76

Key exclusion criteria
1. Inability to give informed consent
2. Significant eczema on the dorsal surface of the hands
3. Previous phototherapy within the last 3 months
4. Previous sunbed use within the last 3 months
5. Current involvement in other investigational studies or trials, or involvement within 3 months prior to study entry

Date of first enrolment
01/08/2012

Date of final enrolment
28/06/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Health and Society 4th Floor William Leech Building
Newcastle Upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Leazes Wing, Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
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NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) - Research for Patient Benefit [RfPB] (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration