

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	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/04/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/08/2016	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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)
Claire.oyston@ncl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Claire Oyston

Contact details
Institute of Health and Society 4th Floor William Leech Building
Framlington Place
Newcastle Upon Tyne
United Kingdom
NE2 4HH
-
claire.oyston@newcastle.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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)

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration