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Predicting remission of psoriasis after phototherapy

Submission date
01/05/2014

Recruitment status
No longer recruiting

Registration date
01/05/2014

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. It is a long-term, disabling condition that affects around 2% of the UK population. UVB (ultraviolet B) light is one of the few treatments which can clear psoriasis completely. Some patients then stay clear for months or even years. The most commonly used form of UVB treatment is narrowband UVB (NbUVB), which is effective in approximately 70% of patients. Many patients completing a course are 'almost clear' on discharge (often with just 1 or 2 small areas remaining), but clinical observation suggests that the psoriasis in these patients may come back quicker than in patients who clear completely. Understanding whether complete clearance of psoriasis is important for prolonged remission will inform effective management of psoriasis patients' potentially providing longer disease remission, and with fewer treatment courses required overall. This may reduce the need for systemic treatment, lead to improved safety, and provide insights into mechanism of remission and relapse. The aim of this study is to find out whether patients whose psoriasis is 100% clear following a course of narrowband UVB have a longer duration of remission than those whose psoriasis was almost clear/didn't clear.

Who can participate?
Adults who have long-term psoriasis and have been prescribed narrowband UVB treatment.

What does the study involve?
Patients who agree to participate attend three times weekly for phototherapy treatment (as for routine treatment). Before starting the course and at the end of the treatment they are asked to provide a blood sample, fill out a questionnaire (DLQI) and have their skin severity score (PASI) measured by nursing staff. The latter is also performed weekly when the patients attend for routine treatment. After 12-15 phototherapy treatments, patients with localised resistant plaques will be allocated at random to receive routine NbUVB or routine NbUVB plus 308nm Excimer treatment to these "resistant" plaques.

What are the possible benefits and risks of participating?
Benefits of participating include possibility of getting greater extent of clearance. Risks of participating are the same as for routine UVB treatment, and include erythema/ burning.

Where is the study run from?
Royal Victoria Infirmary (UK)

When is the study starting and how long is it expected to run for?
January 2013 to October 2016

Who is funding the study?
British Skin Foundation (UK)

Who is the main contact?
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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
15935

Study information

Scientific Title
Is the duration of remission of psoriasis increased after complete clearance versus 'almost complete' clearance following narrowband UVB phototherapy?

Acronym
PROPAP

Study objectives
Patients whose psoriasis is 100% clear following a course of narrowband UVB have a longer duration of remission than those whose psoriasis was almost clear/didn't clear.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Newcastle & North Tyneside 1 Research Ethics Committee, 09/01/2014, ref: 13/NE/0357

Study design
Both; Interventional and Observational; Design type: Not specified, Treatment, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
Patients will be given written information about the study and asked to give informed consent to participate. Patients will be given at least 48 hours to decide if they wish to participate. If they agree to take part demographic data will be collected, and the patients PASI and BMI recorded prior to the start of treatment. Demographic data will include the age that the patient first developed psoriasis, length of current episode/ flare, plaque size and presence of scalp involvement. We will also record any topical treatment that the patient has been using in the fortnight leading up to phototherapy. Patients will be asked to give a blood test prior to treatment (for CRP and vitamin D levels), and at the end of treatment period. Dermatology life quality index (DLQI) will be measured before treatment and after the treatment is complete.

Patients will then begin their routine NbUVB (narrow band ultraviolet B) treatment as per the normal protocol; weekly PASI scores will be recorded throughout treatment to assess their progress. After 15 treatments, patients still receiving treatment will be randomised to receive targeted narrowband UVB (308 Excimer Lamp) to up to 5 of the most treatment resistant plaques (usually the thickest plaques), or to be observed (see flow diagram below). Randomisation will be performed using SealedEnvelope.com (1:1). In our previous study 28% of patients were no longer having UVB treatment after 5 weeks (15 treatments), therefore we

expect to have approximately 70% of recruited patients reaching 16 treatments. All patients will continue with their routine UVB until the end of the course (maximum of 30 treatments).10

At the end of the treatment period all patients will have their psoriasis area and severity (PASI) scores measured and will be given a diary to monitor any recurrence of psoriasis and any potential triggers for this (e.g sore throat, new medication etc). Patients will be telephoned on a monthly basis to ask about recurrence of psoriasis (we will text patients a reminder 24 hours before the phone call to confirm their telephone appointment). If this has been noted by the patient they will be assessed and their PASI measured. If they have a PASI of at least 50% of their pre-treatment level this will be defined as a relapse. If it is less than 50%, patients will be followed up on a monthly basis until relapse has occurred. It is expected that most patients will have relapsed within 12 months of treatment completion, although one study has had patients in remission for up to 22 months.1

Where possible all PASI scores will be measured by the same person, and when cover is required, a colleague experienced in measuring PASI scores will be asked to score the patient. Photographs will be taken of identified plaques of psoriasis before and after the 308nm Excimer Lamp treatment, as per standard protocol.

The expected study end date will be 2 years after the study begins. However as recruitment may take up to 1 year it is possible that we may need to extend the study by 6 months to allow for complete follow up of all patients.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Duration of remission achieved in psoriasis patients following a course of Narrowband UVB (NbUVB) ismeasured through monthly telephone calls after completion of treatment until study end. Patients are recalled and undergo a skin evaluation if psoriasis has flared.When >50% of the original PASI score is reached, the patients involvement in the study is complete.

Secondary outcome measures
1. Duration of remission achieved in patients who achieve “complete” clearance of psoriasis versus those who achieve “almost complete” clearance. Complete clearance was defined as 100%, and almost complete as 75-99% clear.
2. Practicality and effectiveness of the 308nm Excimer lamp in clearing more ‘resistant’ plaques alongside a standard course of NbUVB by nurse questionnaire

Overall study start date
24/01/2013

Completion date
31/10/2016

Eligibility

Key inclusion criteria

1. Age of 18 years or older
2. Gives written informed consent to the study
3. Has chronic plaque psoriasis and has been routinely prescribed narrowband UVB

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
100

Key exclusion criteria
1. Pregnancy
2. Patients on systemic treatment for psoriasis within the past 3 months
3. Patients with significant UV exposure over the past 1 month (sunny holidays /sunbeds etc)
4. Patients with a previous history of malignant skin cancer
5. Non-English speaking patients

Date of first enrolment
24/04/2014

Date of final enrolment
06/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle-upon-Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

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

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
British Skin Foundation

Alternative Name(s)
BSF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Abstracts submitted to the British Association of Dermatologists (meeting July 2017). Planned publication in a high impact peer reviewed journal in approximately March 2018.

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Sophie.weatherhead@nuth.nhs.uk

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/07/2017	10/05/2021	No	No
HRA research summary			28/06/2023	No	No