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Starting dose of ultraviolet B to treat psoriasis

Submission date	Recruitment status	[_] Prospectively registered
03/12/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/11/2010	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NRR N0405128578

Study information

Scientific Title

A randomised comparison of methods of selecting narrow-band ultraviolet B starting dose to treat chronic psoriasis

Study objectives
Does the method of selecting narrowband ultraviolet B (NB-UVB) starting dose, whether based upon individual patient minimal erythemal dose (50% or 70%) or not, alter efficacy or adverse effects of narrowband ultraviolet B phototherapy to treat chronic psoriasis?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside local regional ethics committee (LREC) approved in 2003 (ref: 109/03)

Study design
Randomised 3-arm triple blind parallel group trial

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
Psoriasis; dermatological disease

Interventions
Narrowband ultraviolet B phototherapy: administered as routine except for decision on start dose. The method of deciding first narrowband ultraviolet B dose was randomised:
1. Start dose 70% minimal erythemal dose
2. Start dose 50% minimal erythemal dose
3. Start dose skin phototype based

Treatments were administered 3-times weekly. Duration of treatment and study follow-up was until clearance or minimal residual activity (MRA). The total number of treatments varied (all groups median 27 treatments, maximum 61 treatments) and duration of attending for treatment was median 10 weeks (maximum 34 weeks). The apparent discrepancy (e.g. 34 weeks corresponding to 61 treatments is because not all patients always attended every week 3-times

per week).
There was no study follow up phase after completion of treatment course many patients have been followed up longer, but not as part of this study.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Number of narrowband ultraviolet B treatments to clearance of psoriasis
2. Number of important (uncomfortable or painful) erythema episodes occurring during treatment courses

Secondary outcome measures
1. Change in Psoriasis Disability Index (Finlay AY, Khan GK, Luscombe DK, Salek MS. Validation of Sickness Impact Profile and Psoriasis Disability Index in Psoriasis. Br J Dermatol. Dec 1990;123(6): 751-756.)
2. Change in Psoriasis Area and Severity Index
Both outcomes above were measured at baseline before the first UVB treatment, the 15th and the last treatment visit.

Overall study start date
15/12/2003

Completion date
15/10/2007

Eligibility

Key inclusion criteria
All patients referred for NB-UVB phototherapy for chronic (defined as present for more than one year) psoriasis (as diagnosed by a dermatologist), from our catchment area

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
210 (70 in each arm)

Key exclusion criteria
1. Less than 16 years old
2.On systemic immunosuppressant therapy or retinoids within the preceding three months

Date of first enrolment
15/12/2003

Date of final enrolment
15/10/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Photobiology Unit, Department of Dermatology
Dundee
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DD1 9SY

Sponsor information

Organisation
NHS Tayside (UK)

Sponsor details
Research & Development
Ninewells Hospital and Medical School
Dundee
Scotland
United Kingdom
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Other

Funder Name
NHS Tayside (UK) - Photobiology Unit Charitable Trust

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2011		Yes	No