ISRCTN10725589 https://doi.org/10.1186/ISRCTN10725589

Ultraviolet Light (UV) Therapy for Atopic Dermatitis: Double blind, randomised trial of narrow band (TLO1) versus UVA versus placebo.

Submission date	Recruitment status
23/01/2004	No longer recruiting
Registration date	**Overall study status**
23/01/2004	Completed
Last Edited	**Condition category**
15/12/2009	Skin and Connective Tissue Diseases

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

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

94090017 R140/05081

Study information

Scientific Title

Study objectives
There is a need for safe alternative therapies to emollients and topical steroids in atopic dermatitis. Recent non-blinded studies suggest that ultraviolet A (UVA) and narrow band width UVB (TLO1) phototherapy may be effective in atopic dermatitis. We propose to study 75 adult patients, age 16-65 years with moderate severe atopic dermatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double blind randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Skin and connective tissue diseases:

Interventions
1. TLO1-UVB
2. UVA
3. Placebo phototherapy

Initial dose of UVA will be 5 J/sq cm, increased to 10 then 15 J/sq cm as tolerated. Initial dose of TLO1 will be increased from 0.4, to 0.6, to 0.9, to 1.2 J/sq cm until mild erythema develops and then according to a defined protocol. Visible fluorescent lamps will be employed for placebo treatments. Treatments will be twice weekly for a maximum of 24 exposures.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Preliminary work suggests a response should be detectable after 12 treatments. Physical signs of disease activity, overall extent of disease, patient symptoms and quantities of topical steroids used will be assessed, by an observer who is unaware of treatment received, at baseline, after 6, 12, 18 and 24 treatments and 3 months after stopping phototherapy.

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/06/1996

Completion date
30/06/1998

Eligibility

Key inclusion criteria
Patients, aged 16-65 years with moderate severe atopic dermatitis.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
75

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/06/1996

Date of final enrolment
30/06/1998

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Dermatology
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
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+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/06/2001		Yes	No