

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

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/12/2009	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Nicholas Reynolds

Contact details
Department of Dermatology
Medical School
Framlington Place
Newcastle upon Tyne
United Kingdom
NE2 4HH
+44 (0)191 222 8936
n.j.reynolds@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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
SW1A 2NL
+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