

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	☐ Prospectively registered
Registration date 23/01/2004	Overall study status Completed	☐ Protocol
Last Edited 15/12/2009	Condition category Skin and Connective Tissue Diseases	☐ Statistical analysis plan
		☒ 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

Protocol serial number
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

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s))

Not provided at time of registration

Completion date

30/06/1998

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Department of Dermatology

Newcastle upon Tyne

United Kingdom

NE2 4HH

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

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