

Side by side comparison of 0.03% tacrolimus ointment (Protopic) versus usual topical steroid treatment in children with atopic dermatitis

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/04/2008	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0129118582

Study information

Scientific Title

Study objectives

In children with moderately severe atopic dermatitis is Protopic more effective than the usual steroid ointment in controlling disease activity?

There is only limited information concerning the relative efficacy of topical tacrolimus versus topical corticosteroids in the treatment of atopic dermatitis in children. The aim of this study was to determine the usefulness of tacrolimus ointment in the treatment of children with moderately severe atopic dermatitis currently receiving topical corticosteroids.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Skin and Connective Tissue Diseases: Atopic dermatitis

Interventions

Randomised controlled trial with random allocation to: [A] Protopic and [B] usual steroid ointment. Fifty children attending the regional eczema referral outpatient clinic at Booth Hall Children's Hospital will be randomised to apply Protopic ointment to one arm or leg and the effectiveness of this treatment will be compared with continuing application of the usual steroid to the other limb. The doctor, who will be blinded to which side the Protopic is applied, will assess the patient 1 week later to determine which treatment is more effective.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Protopic

Primary outcome measure

Comparison of the severity of eczema on the side to which the Protopic is applied compared with the other limb.

Secondary outcome measures

Atopic dermatitis

Overall study start date

01/11/2002

Completion date

01/11/2004

Eligibility**Key inclusion criteria**

50 children

Participant type(s)

Patient

Age group

Child

Sex

Not Specified

Target number of participants

50

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/2002

Date of final enrolment

01/11/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Child Health

Manchester

United Kingdom

M9 7AA

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Central Manchester and Manchester Children's University Hospitals NHS Trust (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	01/03/2007		Yes	No