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

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/04/2008	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
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