

A randomised double-blinded cross-over trial comparing betamethasone valerate and tacrolimus ointment for the treatment of moderate to severe atopic eczema

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/04/2015	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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The Middlesex Hospital
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London
United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A randomised double-blinded cross-over trial comparing betamethasone valerate and tacrolimus ointment for the treatment of moderate to severe atopic eczema

Study objectives

Is tacrolimus more efficacious than betamethasone valerate ointment in moderate to severe atopic dermatitis?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double-blinded cross-over trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Skin and Connective Tissue Diseases: Atopic dermatitis

Interventions

1. Steroid ointment
2. Other ointment

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Betamethasone valerate and tacrolimus ointment

Primary outcome measure

SCORAD score (numerical assessment score of patient symptoms, range 0-103). Ointment weight. Recording of side-effects noted.

Secondary outcome measures

Not provided at time of registration

Overall study start date

31/01/2003

Completion date

01/10/2005

Eligibility**Key inclusion criteria**

100 patients from Dermatology

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

31/01/2003

Date of final enrolment

01/10/2005

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

The Middlesex Hospital
London
United Kingdom
W1N 8AA

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Government

Funder Name
University College London 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