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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

Registration date
30/09/2004

Overall study status
Completed

Last Edited
17/04/2015

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0263128762

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