

A clinical trial to evaluate the efficacy and safety of Altoderm™, a topically-applied sodium cromoglicate lotion, in the treatment of atopic dermatitis (eczema) in children

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| Submission date 24/03/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 30/04/2009 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 24/06/2016 | 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1387 T&R SkinP.02

Study information

Scientific Title

A multicentre, double-blind, vehicle-controlled, randomised group-comparative study to evaluate the efficacy and safety of Altoderm™, a topically-applied sodium cromoglicate lotion, in the treatment of atopic dermatitis in children

Study objectives

Sodium cromoglicate, a drug used in the treatment of allergic diseases, asthma, rhinitis, conjunctivitis and food allergy will be an effective and safe treatment for atopic dermatitis (eczema) in children, when applied topically to the skin.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands Research Ethics Committee approved on the 20th January 2009 (ref: 08/H1208 /57)

Study design

Multicentre double blind randomised parallel-group study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Atopic dermatitis (eczema)

Interventions

Active: a 4% solution of sodium cromoglicate in an aqueous lotion base

Control: the aqueous lotion base (vehicle)

Both treatments are applied to the affected areas of skin, twice daily. The total intervention period is 12 weeks; the total trial period is 16 weeks. There is a 4 week baseline period when all continue with existing treatment which must include an emollient. There is no follow-on period.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Sodium cromoglicate (Altoderm™)

Primary outcome measure

Change from baseline in SCORAD score and in the skin itch element of the SCORAD score at the end of the trial.

Secondary outcome measures

1. Change from baseline in Six Area, Six Sign Atopic Dermatitis (SASSAD) score, estimated at each clinic visit, 7 times in total
2. Change from baseline in severity of overall skin condition, skin itch and sleep disturbance as measured on a daily diary card, recorded daily by the parent throughout the baseline and treatment period and analysed in 2 week blocks
3. Change from baseline in usage of topical steroid therapy as determined by daily use as recorded on diary cards (proportion of days used and times used per day), and weight of topical steroid used, recorded daily by the parent and amount used weighed and recorded each day. The results will be analysed in 2 week blocks.
4. Change from baseline in steroid use as recorded by Investigator at each clinic visit, recorded daily by the parent and amount used weighed and recorded each day. The results will be analysed in 2 week blocks.
5. Change from baseline in quality of life questionnaire using the Children's Dermatology Life Quality Index (CDLQI) or Infant's Dermatitis Quality of Life Index (IDQOL), completed at visits 1, 3, 5 and 7
6. Global opinions (parent and investigator) of efficacy of treatment and acceptability, recorded at the final clinic visit
7. Incidence of adverse events

Overall study start date

01/04/2009

Completion date

31/07/2010

Eligibility

Key inclusion criteria

At screening:

1. Children of either sex aged over 2 years but less than 12 years (after 2nd birthday and before 12th birthday)

2. Children with atopic dermatitis according to criteria of the UK Working Party for diagnostic criteria for atopic dermatitis. These are:
 - 2.1. Must have an itchy skin condition (or report of scratching or rubbing in a child)
 - 2.2. Three or more of the following:
 - 2.2.1. History of itchiness in skin creases such as folds of the elbows, behind the knees, fronts of ankles, or around the neck (or the cheeks in children less than 4 years)
 - 2.2.2. History of asthma or hay fever (or history of atopic disease in a first degree relative in children under 4 years)
 - 2.2.3. General dry skin in the past year
 - 2.2.4. Visible flexural eczema (or eczema affecting the cheeks or forehead and outer limbs in children under 4 years)
 - 2.2.5. Onset in the first two years of life
3. Children who have a SCORing Atopic Dermatitis (SCORAD) of greater than or equal to 25 and less than or equal to 60
4. Children with atopic dermatitis whose parent(s) agree to:
 - 4.1. Keep daily diary cards throughout the 16 weeks of the study, in order to record:
 - 4.1.1. The weight and number of times, each day, they use their emollients and topical steroids during the baseline and emollients, topical steroids and test medication during the double-blind period
 - 4.1.2. The child's eczema (skin condition, itching and sleep disturbance on a 4 point scale)
 - 4.2. Ensure that their emollient is applied at least twice daily throughout the baseline period (weeks 1 - 4) but only as required during the double blind period (weeks 5 - 16)
5. Children who are able, in the investigator's opinion, to understand the issues, give signed, informed consent to participate in the trial
6. Children of parents (or legal guardians) who give signed, informed consent to participate in the trial

At entry to double blind period:

Children who, having been treated with emollients on a regular basis for 4 weeks (baseline period), have a SCORAD of greater than or equal to 25 and less than or equal to 60 and diary card scores for skin itch and overall skin condition of 2 or greater (using a 0 - 3 scale), on at least 4 days of the last 14 days of the baseline period.

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

180

Key exclusion criteria

1. Children with any other chronic disease with the exception of those associated allergic diseases (such as recurrent wheezing, allergic rhinitis and food allergy) should be excluded
2. Children who have cardiovascular, neurological, hepatic, renal, gastrointestinal, or other significant acute or chronic medical indication which, in the judgement of the investigator, might interfere with the study or required treatment
3. Patients who have received oral corticosteroids or corticosteroids by injection within the past 2 months
4. Patients currently using wet wrapping or calcineurin immunomodulators or have used wet wrapping during the previous 7 days or calcineurin immunomodulators during the previous 4 weeks

Date of first enrolment

01/04/2009

Date of final enrolment

31/07/2010

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Maple Tree Cottage

Sidmouth

United Kingdom

EX10 9TU

Sponsor information**Organisation**

Thornton & Ross Ltd (UK)

Sponsor details

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Sponsor type

Industry

Website

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ROR

<https://ror.org/00frd0c49>

Funder(s)

Funder type

Industry

Funder Name

Thornton & Ross Ltd (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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| HRA research summary | | | 28/06/2023 | No | No |