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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

Submission date
24/03/2009

Recruitment status
No longer recruiting

Registration date
30/04/2009

Overall study status
Completed

Last Edited
24/06/2016

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

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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
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Sponsor information

Organisation
Thornton & Ross Ltd (UK)

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Sponsor type

Industry

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http://www.thorntonross.com/

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