

# 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

<b>Submission date</b> 24/03/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/04/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/06/2016	<b>Condition category</b> 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**  
Dr Alan Edwards

**Contact details**  
Maple Tree Cottage  
Manstone Lane  
Sidmouth  
United Kingdom  
EX10 9TU  
+44 (0)1395 576 696  
aedwards@vectis-allergy.com

## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

### **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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

2 years

**Upper age limit**

12 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**  
**Maple Tree Cottage**  
Sidmouth  
United Kingdom  
EX10 9TU

## Sponsor information

**Organisation**  
Thornton & Ross Ltd (UK)

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

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Thornton & Ross Ltd (UK)

## Results and Publications

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes