

# A trial of topical sodium cromoglicate in atopic dermatitis in children

<b>Submission date</b> 14/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/08/2008	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Kai-Håkon Carlsen

**Contact details**  
Voksentoppen BKL  
National Hospital (Rikshospitalet)  
Ullveien14  
Oslo  
Norway  
NO 0791

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
T&R.SkinP.01

## Study information

## **Scientific Title**

### **Acronym**

T&R.SkinP.01

### **Study objectives**

Sodium cromoglicate lotion applied topically to the skin is more effective than the vehicle in the treatment of atopic dermatitis in children.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Atopic dermatitis

### **Interventions**

Parallel group comparative randomised controlled trial:

1. 4% sodium cromoglicate in an aqueous lotion
2. The aqueous lotion vehicle

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

The change in the SCORAD assessment score between end of baseline and after 12 weeks treatment.

## **Secondary outcome measures**

1. The change in overall skin condition, itch and sleep disturbance recorded on the daily diary cards
2. The change in topical corticosteroid and/or immunomodulator drug use as recorded on the daily diary cards and by weighing of the tubes
3. The global assessments recorded at the end of the study by the parent and investigator
4. The change in Childrens Dermatology Life Quality Index (CDLQI) or Infant Life Quality Index

## **Overall study start date**

01/10/2005

## **Completion date**

30/06/2007

# **Eligibility**

## **Key inclusion criteria**

1. Children of either sex aged between 1 and 12 years (after the first birthday and before the 13th birthday)
2. Children with atopic dermatitis according to 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. Plus 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 with atopic dermatitis who at the Screening Visit (Visit 1) and at Visit 2 exhibit a score using the SCORing Atopic Dermatitis (SCORAD) scoring system for atopic dermatitis of greater than or equal to 25
4. Children of parents, one of whom gives signed, informed consent to participate in the trial

## **Participant type(s)**

Patient

## **Age group**

Child

## **Lower age limit**

1 Years

## **Upper age limit**

12 Years

## **Sex**

Both

**Target number of participants**

174

**Key exclusion criteria**

1. Children with any chronic disease other than associated allergic diseases (which include recurrent wheezing, allergic rhinitis and food allergy)
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 require treatment
3. Patients who have received oral corticosteroids or corticosteroids by injection within the past 3 months

**Date of first enrolment**

01/10/2005

**Date of final enrolment**

30/06/2007

**Locations****Countries of recruitment**

Norway

United Kingdom

**Study participating centre**

Voksentoppen BKL

Oslo

Norway

NO 0791

**Sponsor information****Organisation**

Thornton and Ross Ltd (UK)

**Sponsor details**

Stephen J Skilleter

Thornton & Ross Ltd

Linthwaite

Huddersfield

United Kingdom

HD7 5QH

**Sponsor type**

Industry

**Website**

<http://www.thorntonross.com>

**ROR**

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

## Funder(s)

**Funder type**

Industry

**Funder Name**

Thornton and 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?
<a href="#">Results article</a>	Results	01/02/2005		Yes	No