

A trial of topical sodium cromoglicate in atopic dermatitis in children

Submission date

14/09/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

12/10/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

14/08/2008

Condition category

Skin and Connective Tissue Diseases

☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 Years

Upper age limit

12 Years

Sex

All

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

United Kingdom

Norway

Study participating centre

Voksentoppen BKL

Oslo

Norway

NO 0791

Sponsor information

Organisation

Thornton and Ross Ltd (UK)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Thornton and 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?
Results article	Results	01/02/2005		Yes	No