# Effectiveness of different strenghts of topical steroids in children with eczema in general practice.

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21308

**Source**
NTR

**Brief title**
The Rotterdam Eczema study

**Health condition**

Atopic dermatitis

### Sponsors and support

**Primary sponsor:** Erasmus Medical Center
**Source(s) of monetary or material Support:** SBOH

### Intervention

### Outcome measures

**Primary outcome**

Primary outcome will be change in subjective disease severity after 24 weeks follow-up in the trial, measured with Patient-Oriented Eczema Measure (POEM) questionnaire.

**Secondary outcome**

Secondary outcomes concerning trial

- Changes in subjective disease severity after 1 week and 4 weeks of FU (POEM)

- Changes in objective disease severity after 1 week, 4 weeks and 24 weeks of FU (EASI)

- Quality of life with the IDQOL or CDLQI depending on age

- Compliance

- Local side-effects

- Systemic side-effects

- Time to recovery

- Frequency of flare-ups

- Medication use

- Healthcare use

# Study description

**Background summary**

Rationale:

Atopic dermatitis (AD) or eczema is a chronic, highly pruritic inflammatory skin disease, and is the most common chronic skin disorder in children. Eczema is in the top 10 of highest prevalence disorders in general practice in children up to 18 years

The aim of treatment is to keep the skin condition optimal, prevent flare-ups and treat symptoms as soon as they occur. Treatment is initially started by the general practitioner. According to the recently revised guideline of the Dutch College of General Practitioners (NHG) for AD, a stepwise approach is advocated; when AD is mild to moderate, a mild (class I) to moderate potent (class II) topical corticosteroid (CS) is preferred, while potent (class III) CS is used only when AD is severe. It may be that during a flare up, AD can be best treated intermittent with a potent CS (pulse treatment) in terms of time to recovery, patient satisfaction, amount of CS used, and reconsultations.

Objective:

To determine whether a potent topical corticosteroid (CS) is more effective than a mild topical CS in the treatment of children with a moderate flare-up of atopic dermatitis (AD) in primary care on short and long term.

Study design:

Prospective cohort study with an embedded open-label randomized controlled trial.

Study population:

Patients with the diagnosis AD, aged between 12 weeks and 18 years, who visited the GP for AD or received repeated prescription for AD in previous 12 months.

Intervention:

The intervention group will start with a potent CS (class III) at a flare-up of the AD.

Main study endpoints:

Changes in subjective disease severity after24 weeks follow-up in the trial, measured with a recommended and validated questionnaire for patients with AD (POEM).

### Study objective

Class III corticosteroid is more effective than a class I corticosteroid for treating a moderate flare-up of atopic dermatis in children.

### Study design

Subjects will be asked to complete a weekly questionnaire (POEM) for 24 weeks.

At baseline, 1, week, 4 weeks and 24 weeks of follow-up Eczema Area and Severity Index (EASI) will be scoired.

### Intervention

The intervention group will start with a potent corticosteroid (class III) when having a flare-up of the atopic dermatitis. The GP-guideline group will receive treatment according to the Dutch GP-guideline (start with mild CS class I).

## Contacts

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# Eligibility criteria

## Inclusion criteria

In order to be eligible to participate in the cohort study (and possibly be eligible for the trial), a subject must meet all of the following criteria:

- Age >12 weeks and < 18 years

- Diagnosis of eczema (ICPC-code or prescription of topical treatment of eczema) + confirmation of the diagnosis by the GP

- Consultation or repeated prescription in previous 12 months

- Informed consent

In order to be eligible to participate in the trial, a subject must meet all of the following criteria:

- Participation in cohort (see above)

- Flare-up (i.e. need to intensify topical treatment) from patients and/or parents point of view

- TIS-score ≥3 and <6

## Exclusion criteria

A potential patient who meets any of the following criteria will be

excluded from participation in the cohort study:

- As determined by the GP (e.g. family problems)

- Currently under treatment of a dermatologist

- Language barrier

- No access to internet (necessary to fill in weekly online questionnaire)

- Contra-indications for the study medication:

 previously si-e effects with any of the medications

, hypersensitivity to corticosteroids

A potential patient who meets any of the following criteria will be excluded from participation in the trial:

- Use of CS in 2 weeks before inclusion in trial

- >50% of body affected

- Other skin disorders hampering proper assessment of eczema

- Pregnancy and or breastfeeding

- Contra-indications for the study medication:

 untreated skin infections caused by a bacterium, virus, fungal, or parasite

 incurable wounds, ulcerative skin disorders

 ichthyoses, acne vulgaris, rosacea, juvenile plantar dermatosis, skin atrophy, skin lesions

 diaper rash

 perianal and genital itching

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-11-2017 |
| Enrollment: | 150 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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| Date: | 30-08-2017 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 55693
Bron: ToetsingOnline
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL6492 |

| Register | ID |
| --- | --- |
| NTR-old | NTR6679 |
| CCMO | NL61504.078.17 |
| OMON | NL-OMON55693 |

# Study results