A randomized controlled pilot study comparing the efficacy of topical coal tar to topical corticosteroids in children aged 1 to < 16 years with moderate-severe atopic dermatitis.

Published: 25-01-2017
Last updated: 11-04-2024

To evaluate efficacy of topical treatment with coal tar compared to topical treatment with corticosteroids in children aged 1 to

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON42910

Source
ToetsingOnline

Brief title
Efficacy of topical coal tar in children with atopic dermatitis

Condition

- Epidermal and dermal conditions

Synonym
Atopic dermatitis, atopic eczema

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atopic dermatitis, Topical coal tar, Topical corticosteroids, Treatment

Outcome measures

Primary outcome

The primary outcome is the percentage change in EASI score at week 2.

Secondary outcome

Secondary outcomes: percentage change in EASI score at week 4, EASI-75 at week 2 and week 4, Pruritus VAS, Patient Oriented Eczema Measure (POEM), Patient Global Assessment of Disease Severity (PGA), Health-related Quality of Life (CDLQI), Family impact of childhood Atopic Dermatitis (DFI), number of (treatment-related) adverse events, FLG mutation status, NMF amount in stratum corneum and skin microbiota composition.

Study description

Background summary

Atopic dermatitis (AD) is an inflammatory skin disease, occurring most frequently in children. Currently, topically applied corticosteroids are used as a standard anti-inflammatory treatment. When a corticosteroid with a high potency is used for a long period of time adverse effects like skin atrophy and systemic effects may occur, especially in children. In addition, corticophobia among patients is an issue that warrants alternatives for the treatment of AD in children. An alternative treatment is the topical application of coal tar, which is known to be an effective and safe treatment for AD for ages, and is used in our department for decennia. Although there is convincing evidence in the literature on the safety of coal tar, evidence in the literature on the efficacy of coal tar in the treatment of AD is lacking, especially in children.

Research is needed to provide evidence for guidelines for topical treatment with coal tar in children.

Study objective

To evaluate efficacy of topical treatment with coal tar compared to topical treatment with corticosteroids in children aged 1 to <16 years with moderate to severe AD, based on the percentage change in Eczema Area and Severity Index (EASI) at week 2. Secondary outcomes: percentage change in EASI at week 4, the proportion of patients with EASI-75 at week 2 and week 4, decrease in VAS score for pruritus, changes in patient-reported outcome (POEM and Patient PGA), changes in quality of life (CDLQI), changes in family impact (DFI) and tolerability of both treatments. In addition, we aim to investigate a possible association between a filaggrin (FLG) genotype and efficacy of topical coal tar, and to evaluate changes in Natural Moisturizing Factors (NMF) in the stratum corneum and changes in skin microbiota between patients treated with topical coal tar and topical corticosteroids.

Study design

We aim to conduct an investigator-initiated, parallel-group randomized controlled pilot study comparing the topical application of coal tar to moderate-potency topical corticosteroids.

Intervention

Patients will be randomized in two groups: (1) topical treatment with coal tar or (2) topical treatment with moderate potency corticosteroids for a treatment duration of 4 weeks. After 2 weeks, there is a rescue medication option consisting of additional topical treatment with either corticosteroids or coal tar, depending on the treatment arm.

Study burden and risks

Both treatments used in this trial, are normally used in daily clinical practice. In fact, the only difference between daily clinical practice and this trail, is the randomization of the children in two arms. In addition to the daily clinical practice, the children and their parents will have to fill out questionnaires, which will take a little extra time. In addition, saliva will be collected for DNA isolation, dead cornified cells will be collected for NMF analysis by application of adhesive tapes, and swaps will be taken from the skin for microbiome analysis. These procedures are not painful or frightening for the children. There are no risks associated with participation.

Contacts

Public
Radboud Universitair Medisch Centrum

René Descartesdreef 1
Nijmegen 6525GL
NL
Scientific
Radboud Universitair Medisch Centrum

René Descartesdreef 1
Nijmegen 6525GL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Male or female patients aged between 1 and <16 years of age
- Diagnosis of AD based on the criteria of Hanifin and Rajka
- Moderate to severe AD based on EASI score >7.1

Exclusion criteria

- Hypersensitivity and/or intolerance to topical corticosteroids or topical coal tar
- Indication for systemic therapy or a medical need to use a higher level of topical corticosteroids than moderate potency topical corticosteroids

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2018
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Eumovate ointment
Generic name:	Clobetason butyrate 0.05% ointment
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Hydrocortisone ointment
Generic name:	Hydrocortisone acetate 1% ointment
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Topical coal tar
Generic name:	Pix lihantracis 3% in zinc oxide paste
Product type:	Medicine
Brand name:	Topical coal tar
Generic name:	Solution carbonis detergens 10% in cremor vaselini lanette

Ethics review

Approved WMO Date:	25-01-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-09-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-02-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2016-004542-28-NL
CCMO	NL59682.091.16