A randomized controlled trial evaluating the additional effect of topical coal tar to a topical corticosteroid regimen in patients aged >16 years of age with moderate-severe atopic dermatitis

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To evaluate the additional effect of coal tar treatment to a corticosteroid regimen in adults (aged >16 years of age) with moderate to severe atopic dermatitis, based on the percentage change in Eczema Area and Severity Index (EASI) at week 2....

Ethical review	Approved WMO
Status	Will not start
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON43163

Source
ToetsingOnline

Brief title
Additional effect of topical coal tar in adults 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 NRS, Patient Oriented Eczema Measure (POEM), Patient Global Assessment of Disease Severity (PGA), Health-related Quality of Life (DLQI), 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, often requiring long-term treatment. Currently, topically applied corticosteroids are used as a standard anti-inflammatory treatment. An alternative treatment for AD is topical coal tar, which is known to be an effective and safe treatment for AD for ages, and is used in our department for decennia. Based on our clinical experience, we expect adding topical coal tar to a standard corticosteroid regimen will decrease the severity of AD, and might shorten the duration of treatment. The additional effect of coal tar to a corticosteroid regimen has not been reported to date.

Study objective

To evaluate the additional effect of coal tar treatment to a corticosteroid

regimen in adults (aged >16 years of age) with moderate to severe atopic dermatitis, 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 NRS score for pruritus, changes in patient-reported outcome (POEM and Patient PGA), changes in quality of life (DLQI), 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/or topical corticosteroids, and to evaluate changes in Natural Moisturizing Factor (NMF) levels in the stratum corneum and the skin microbiota between patients treated with topical coal tar and/or topical corticosteroids.

Study design

We aim to conduct a investigator-initiated, parallel group, randomized controlled trial evaluating the efficacy of additional coal tar treatment to a corticosteroid treatment regimen in patients >16 years of age with moderate-severe AD.

Intervention

Patients will be randomized in two groups: (1) topical treatment with coal tar and a potent corticosteroid (class III) or (2) topical treatment with a potent corticosteroid (class III) for a treatment duration of 4 weeks.

Study burden and risks

Both treatments used in this trial are normally used in daily clinical practice. The only difference between daily clinical practice and this trial, is the randomization of the patients in two treatment arms. In addition to daily clinical practice, the participants are asked 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 are all non-invasive procedures. Therefore, we expect the risk for participants to be negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male or female patients aged >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 potent 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:	Will not start
Enrollment:	56
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Betnelan ointment
Generic name:	Betamethasone valerate 1mg/g ointment
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Hydrocortison ointment
Generic name:	Hydrocortisone acetate 1% ointment
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Topical coal tar
Generic name:	Pix lihantracis
Product type:	Medicine
Brand name:	Topical coal tar
Generic name:	Solutio carbonis detergens

Ethics review

Approved WMO

Date:	25-01-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-04-2018
Application type:	First submission
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	EUCTR2016-004687-19-NL
CCMO	NL59928.091.16