A randomized controlled trial to asses the effect of topical vitamin D in patients with atopic dermatitis.

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

Summary

ID

NL-OMON35970

Source
ToetsingOnline

Brief title
Atopic dermatitis and vitamin D

Condition

- Epidermal and dermal conditions

Synonym
atopic eczema

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: reserverekening Dermatologie

Intervention

Keyword: atopic dermatitis, filaggrine, vitamin D

Outcome measures

Primary outcome

Main endpoint will be the number of, and time to, exacerbation of atopic

dermatitis.

To assess a profile of which patients are better to treatable with topical

vitamin D, filaggrin mutation and vitamin D levels at the start of treatment

will be assessed.

Secondary outcome

The quality of life in patients using the different treatment and the

difference of transepidermal water loss between the two treatment groups.

Study description

Background summary

Atopic dermatitis (AD) is a common relapsing chronic skin disease. One of the contributing etiologic mechanisms is an impaired epidermal barrier. The epidermis in AD has a higher proliferation rate, and less differentiation than skin of healthy controls. A loss-of-function mutation in FLG is associated with AD. This gene encodes for filaggrin, an important component of the epidermal barrier.
AD is treated with topical corticosteroids that have several side-effects. Finding new treatment options is therefore needed. Vitamin D has proven to have beneficial effects on AD. Topical vitamin D3 analogues show an improvement of the epidermal barrier, with little to no side-effects, but have never been examined for the effects on AD. Therefore, we will examine the effects of topical vitamin D on AD. The expectation is that administering these ointments to patients with AD will reduce the symptoms.

Study objective

The main study objective is to determine the time to, as well as number of exacerbations of atopic dermatitis in the study period between the study groups A and B.
The secondary objectives are the differences in transepidermal water loss and Quality of Life between the study groups.

Study design

Single blind, randomised control, intervention study

Intervention

Patients in the first group will be treated with the golden standard for atopic eczema: corticosteroid ointment; specifically mometason ointment. The second group of patients will be treated with vitamin D ointment as active treatment. Both groups are allowed to use several kinds of emolliens as maintenance treatment.

Study burden and risks

Burden and risk associated with participation are low. Subjects will be asked to visit the out-patient clinic 3 times, in 4 months. The overall data is acquired by physical examination, non-invasive measurement (quality of live questionnaires and TEWL-measurement) and 2 venapunctures (for assessment of their vitamin D level).
Patients will be asked for permission to check their DNA for a filaggrin mutation; this can be obtained with a cheek swab. Patients are free to refuse this test.
The investigational drug, calcitriol ointment, has already been registered for use in another skin disease and has been shown to have little to no side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18 years or older.
Mild to moderate atopic dermatitis, with a SCORAD score between 15 and 40.
Informed consent

Exclusion criteria

-Oral use of prescribed vitamin D or calcium supplements.
-Pregnancy
-Lactating women
-Patients who receive specialized treatment for disorders in calcium homeostasis and/or liver and kidney diseases.
-Inflammatory skin diseases unrelated to atopic dermatitis, except acneiform eruption.
-Sunny holiday during the previous 6 weeks
-Use of sunbeds or UV-therapy.
-Allergy/intolerance for ingredients used in the study medications.
-Previously documented non-compliance.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-03-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL36662.029.11