Daily vs. weekly showering in atopic dermatitis: a randomized controlled clinical trial.

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To compare the clinical outcome of daily showering followed by immediate application of emollient to once weekly showering followed by immediate application of emollient, in children with mild to moderate AD. The primary outcome parameter will be...

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

Summary

ID

NL-OMON42004

Source
ToetsingOnline

Brief title
WATER study

Condition

- Epidermal and dermal conditions

Synonym
atopic dermatitis, atopic eczema

Research involving
Human

Sponsors and support

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

Intervention

Keyword: atopic dermatitis, bathing, showering, water

Outcome measures

Primary outcome

Comparison of change in objective SCORAD from week 4 compared to week 0 between procedure groups.

Secondary outcome

Comparison of change in Eczema Area and Severity Index (EASI), quality of life, AD symptoms, transepidermal water loss, skin capacitance, natural moisturizing factors and skin lipids in tape strips at week 4 compared to week 0 between procedure groups.

Used amounts of topical medication and Vaseline paraffin ANA and patient*s preference for once weekly vs daily showering at week 4 will be compared between procedure groups.

The change in objective SCORAD from week 4 compared to week 0 will be compared between procedure groups, stratified by mild vs moderate AD, and stratified by light skin types (1, 2, 3) vs dark skin types (4, 5, 6).

Study description

Background summary

Atopic dermatitis (AD) is a common disease in children. There is much uncertainty on how frequent children with AD should shower because of lack of

scientific evidence. In the Dutch guidelines for AD (Richtlijn Constitutioneel Eczeem) no advice is given on this topic, because of lack of evidence. The European guidelines advice daily showering/bathing, but do this based on expert opinion due to lack of trials.The American guidelines conclude that randomized controlled trials to better determine optimal bathing techniques, including controlled studies on frequency, duration, and the effects of bathing and use of bath emollients are a significant gap in research in the management of AD.

Study objective

To compare the clinical outcome of daily showering followed by immediate application of emollient to once weekly showering followed by immediate application of emollient, in children with mild to moderate AD. The primary outcome parameter will be the objective SCORing Atopic Dermatitis (SCORAD).

Study design

This will be a randomized, controlled, observer blinded, superiority clinical trial with two parallel groups.

Intervention

Each patient is assigned a randomization number according to a computer generated randomization. Randomization will be performed with a 1:1 allocation. One group will shower once daily every day according to a standard protocol for 4 weeks; the other group will shower once weekly according to a standard protocol for 4 weeks. All patients will use emollients daily and will be allowed to continue topical medication (except tar ointments) as prescribed by their dermatologist.
Patienst will be evaluated at the start and end of the study. During these visits the severity of AD will be scored, 4 questionnaires on AD symptoms and quality of life will be obtained, non-invasive skin measurements of transepidermal water loss and skin capacitance will be performed, and tape strips will be obtainen. This interventions are painless. In week 2 of the study a telephone consultation will take place to discuss possible questions etc. the patients may have.

Study burden and risks

Participation in this study implies no health risks and little discomfort. Patients are allowed to continue medical care (except for tar ointments) for their AD. In current practice, patients exhibit varying bathing habits, ranging from once a month to twice daily. The 2 chosen shower regimens are therefore suitable with examples from common practice. The tape stripping is painless and without any side effects. TEWL and skin capacitance measurements are non-invasive and without any side effects. There is no direct benefit for the

participants.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Male or female patients with atopic dermatitis (AD) according to the UK working party criteria
Age 4-12 years
Mild to moderate AD (objective SCORAD < 40)
Having access to a shower
Presence of 1 AD lesion and a part of non-lesional skin on preferably the ventral (fore) arm

Exclusion criteria

Active skin infection requiring antibiotic treatment
Systemic immunomodulatory treatment (for AD or other diseases)
Intolerance to Vaseline paraffin ANA
Unwillingness to use Vaseline paraffin ANA as sole emollient
Usage of tar ointments
Usage of thin bleach baths
Performance of water sports (swimming etc) more than once a week

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):	09-07-2015
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO

Date:	09-04-2015
Application type:	First submission
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	NL52319.018.15