WATER study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24085

Source
Nationaal Trial Register

Brief title
WATER study

Health condition

atopic dermatitis, atopic eczema, water, showering, bathing, emollient.

atopisch eczeem, constitutioneel eczeem, water, douchen, baden, emolliens

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam, The Netherlands
Source(s) of monetary or material Support: Academic Medical Center, Amsterdam, The Netherlands

Intervention

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

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 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.

Countries of recruitment: Patients will be recruited in The Netherlands.

Study objective

Daily showering followed by immediate application of emollient is better for the clinical outcome of mild to moderate AD in children, when compared to once weekly showering followed by immediate application of emollient.

Study design

At the start (day 1) and the end (day 28) of the study

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.

Contacts

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Eligibility criteria

Inclusion criteria

Male or female patients with AD according to the UK working party criteria

Age 4 to 11 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

Written informed consent of both parents/ legal representative(s)

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-07-2015
Enrollment:	46
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-07-2015
Application type:	First submission

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
NTR-new	NL5163
NTR-old	NTR5303
Other	Medisch ethische commissie van het Academisch Medisch Centrum, Amsterdam : METC 2015_023

Study results