Wet-wrap treatment in children with atopic dermatitis using the wet-wrap method with diluted corticosteroids versus emollients

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21806

Source
NTR

Brief title
Wet-wrap study in atopic dermatitis

Health condition

atopic dermatitis
atopic eczema
wet-wrap therapy
atopisch eczeem
constitutioneel eczeem
emollients

Sponsors and support

Primary sponsor: Charlotte van Sassen, KinderHaven, Havenziekenhuis Rotterdam
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

The main endpoint concerns the comparison of the decrease of the objective SCORAD between the two groups for the various time points (=comparison of efficacy of the two therapies).

Secondary outcome

One secondary endpoint is the change of serum markers levels at various time points in the two groups and the correlation of the serum markers levels to the objective SCORAD (=development of an effective and objective value for monitoring the severity of AD)
Another secondary endpoint is change in quality of life-score at the beginning and the end of the study in the two groups and the correlation of the quality of life score to the objective SCORAD and the serum markers.

Study description

Background summary

Rationale: Throughout the world, wet wrap therapy is advocated by dermatologists for treatment of children with severe atopic dermatitis. However, there is no consensus regarding the best method for wet wrap therapy with respect to the ointment or cream to be used under the wet dressings.
Objective: The main objective of this study is to compare the efficacy of wet wrap therapy with diluted corticosteroids versus wet wrap therapy with emollients. The secondary objectives are to develop an effective and objective value for monitoring the severity of atopic dermatitis, to monitor quality of life during therapy and to evaluate the safety of both therapies.
Study design: A prospective, double-blind, randomised, multi center intervention study.
Study population: Children 6 months-6 years old with severe atopic dermatitis (objective SCORAD ¡Ý 40).
Intervention: Patients will be randomised over 2 groups: the first group receives therapy with diluted corticosteroid cream under wet wraps and the second group receives emollients under wet-wraps.
Main study endpoint: The main endpoint of the study is the comparison of the decrease of the objective SCORAD between the two groups for the various time points.

Study objective

Wet-wrap treatment with diluted corticosteroids is more effective than wet-wrap treatment with emollients only

Study design

Day 1, 4, 7, 14, 28.

Intervention

Wet-wrap therapy with diluted corticosteroid cream (mometason-furoaat with vaseline 20% cetomacrogolcream dilution 1:19 face and 1:3 body) vs. wet-wrap therapy with emollients (vaseline 20% cetomacrogolcream).

Contacts

Public
(Kinder)dermatologie
Erasmus MC en KinderHaven, Rotterdam
Arnold P. Oranje
Rotterdam
The Netherlands
+31(010) 703 6656/6653/2697 of (010) 404 3700
Scientific
(Kinder)dermatologie
Erasmus MC en KinderHaven, Rotterdam
Arnold P. Oranje
Rotterdam
The Netherlands
+31(010) 703 6656/6653/2697 of (010) 404 3700

Eligibility criteria

Inclusion criteria

1. Age 6 months - 6 years at inclusion

2. Diagnosis of atopic dermatitis with an objective SCORAD > 40

3. Parent/legal guardian willing to comply with the protocol

4. Written, dated consent for subject to participate

Exclusion criteria

1. Known pre-existing, serious underlying disease

2. (Secondary) infected eczema:

- In case of overt impetiginisation, wet wrapping should be delayed until 48-72 hours after commencing antibiotics and confirmation of appropriate treatment by skin swab results

- Eczema herpeticum is an absolute contraindication for the use of wet dressings

3. Signs and symptoms of systemic infection (such as fever, defined as a temperature equivalent to a rectal temperature greater than 38.3ºC)

4. Problems in the hypothalamus-pituitary-adrenal (HPA) axis

5. Systemic corticosteroid therapy

6. Severe growth retardation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL1201
NTR-old	NTR1246
Other	MEC : 2008-077
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A