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

Gepubliceerd: 06-03-2008 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21806

Bron
NTR

Verkorte titel
Wet-wrap study in atopic dermatitis

Aandoening

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

Ondersteuning

Primaire sponsor: Charlotte van Sassen, KinderHaven, Havenziekenhuis Rotterdam
Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Day 1, 4, 7, 14, 28.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2008
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1201
NTR-old	NTR1246
Ander register	MEC : 2008-077
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A