Does local application of betamethasonvalerate 0,1% cream twice a day reduce the complaints of chronic chillblains?

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Chronic chilblains is a common disease causing major restrictions in daily life, nevertheless little is known about treatment. In a literature search, we found thin evidence of three interventions: fluocinolone cream, nifedipine and vitamin D3....

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22759

Bron
NTR

Verkorte titel
BCCC

Aandoening

Chronic perniones
Chilblains

Ondersteuning

Primaire sponsor: Radboud University Nijmegen
department Womens Studies Medicine
(head: Prof. Dr. A.L.M. Lagro Janssen).
Overige ondersteuning: ZonMw program Common Diseases
projectnumber 4201.1006

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

We consider the intervention to be effective when a reduction of complaints or disability occurs of 10mm, as recorded by the subjects on a 100mm Visual analogue scale.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Chronic chilblains is a common disease causing major restrictions in daily life, nevertheless little is known about treatment. In a literature search, we found thin evidence of three interventions: fluocinolone cream, nifedipine and vitamin D3. This study investigates the possible effectiveness of corticosteroid cream.

Objective:

Does local aplication of betamethasonvalerate 0,1% cream twice a day reduce the complaints of chronic chilblains?

Methods:

The design of the study is a double blind crossover type Randomized Clinical Trial. The study population consist of patients with a confirmed diagnosis. Outcome measurement is the change in severity of the complaints and disability as recorded by the subjects on a 100mm Visual Analogue Scale.

Statistical analyses wil be performed using the repeated measures mixed effects model and with regard to possible temperature change during the rechearch period.

Doel van het onderzoek

Chronic chilblains is a common disease causing major restrictions in daily life, nevertheless little is known about treatment. In a literature search, we found thin evidence of three

interventions: fluocinolone cream, nifedipine and vitamin D3. Objective of this study is to study the possible effectivity of betamethasonvaleraat 0,1% cream on the complaints of chronic chilblains.

Onderzoeksopzet

Measuring instrument is a diary used by the subject to record the experienced itch, pain and disability on a 100mm Visual analoge scale (one for each item) on a daily basis. Exposure to cold is registered daily using records of the Royal Netherlands Meteorological Institute (KNMI). There will be 6 face to face contacts: Intake (t1), end of week 1 (t2), end of week 4 (t3), end of week 7 (t4), end of week 10 (t5) and end of week 13 (t6).

Primary and secondary outcomes are evaluated using data before and after intervention or placebo treatment (using data from t2, t4 and t6).

Statistical analyses wil be performed using the repeated measures mixed effects model and with regard to possible temperature change during the rechearch period.

Onderzoeksproduct en/of interventie

Local application on the affected skin parts of betamethasonvalerate 0,1% cream twice a day for a period of six weeks.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Population:

Patients with complaints of chronic chillblains referred to us in the winters of 2009-2010, 2010-2011 and 2011-2012 by GPs in the north west of the Netherlands. And subjects who attended our 2003-2004 study on the effect of vitamin D3.

Inclusion criteria:

1. Age: As of 18 years old;

2. Able to follow instructions and complete a diary;

3. At least 3 weeks of complaints at inclusion: Itching or painful lesions at fingers, toes or other places at the feet or te thighs (the Kibes). The complaints started in the period december to february. There may be swelling and there may be ulceration but these criteria are not obligate.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A patient history of inflammatory disease;

2. Pregnancy;

3. Breast feeding;

4. Actual use of a calcium entry blocker;

5. Use of corticosteroid containing cream or ointment in the past four weeks;

6. Ulcera on the places to be treated.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	60
Type:	Werkelijke 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	NL2054
NTR-old	NTR2171
Ander register	UMC St Radboud/Radboud University : R0000302/Perniones2
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A