

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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22759

Source

NTR

Brief title

BCCC

Health condition

Chronic perniones
Chilblains

Sponsors and support

Primary sponsor: Radboud University Nijmegen
department Womens Studies Medicine
(head: Prof. Dr. A.L.M. Lagro Janssen).

Source(s) of monetary or material Support: ZonMw program Common Diseases
projectnumber 4201.1006

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary we register side effects: skin irritation and signs of skin atrophy.

Study description

Background summary

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 application of betamethasone valerate 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 consists 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 will be performed using the repeated measures mixed effects model and with regard to possible temperature change during the research period.

Study objective

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.

Study design

Measuring instrument is a diary used by the subject to record the experienced itch, pain and disability on a 100mm Visual analogue 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 will be performed using the repeated measures mixed effects model and with regard to possible temperature change during the research period.

Intervention

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

Contacts

Public

Middelie 91
I.H. Souwer
Middelie 1472 GT
The Netherlands
+31 (0)299 621350

Scientific

Middelie 91
I.H. Souwer
Middelie 1472 GT
The Netherlands
+31 (0)299 621350

Eligibility criteria

Inclusion criteria

Population:

Patients with complaints of chronic chilblains 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 the 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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	60
Type:	Actual

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	NL2054
NTR-old	NTR2171
Other	UMC St Radboud/Radboud University : R0000302/Perniones2
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A