Does Nifedipine 60 mg per day per os reduce the complaints of chronic chilblains.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27062

Source
NTR

Brief title
NCCC

Health condition

Chronic Chilblains
Perniones

Perniones
Winterhanden
Wintertenen

Sponsors and support

Primary sponsor: Prof. A.L.M. Lagro-Janssen, MD, PhD, General Practitioner
Radboud University Nijmegen
General Practice/Family Medicine
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Source(s) of monetary or material Support: ZonMw program Common Diseases

Intervention

Outcome measures

Primary outcome

We consider the intervention effective if a reduction of the experienced complaints is discovered, displayed in a decline
of the score "complaint" with at least 10 mm on the visual analogue scale concerned.
"Complaint" is defind as Max
(itch,pain): the Vas score for itch or pain, depending on the highest score.

Secondary outcome

Secondary we register scores for impairment
and the experienced side effects, skin irritation, and symptoms of skin atrophy: purpurae, inclination to bleed and
depigmentation.

Study description

Background summary

Background of the study:

Chilblained hands, toes and thighs form an acute and clinical picture labelled as perniones. Chronic perniones is a nasty and painful disorder often returning every winter and can cause considerable limitations in every day life. Little is known about nature and treatment. There is uncertainty about incidence and prevalence. Data of the Continual
Morbidity Registration point to four new cases per GP per year, mostly women. Prevalence is probably significantly
higher, also in our experience so far.

There is limited evidence for three interventions: Vitamin D3, nifedipine and corticosteroïd cream.

We have already proven the unlikeliness of a positive effect of Vitamin D3.

Indications for possible positve effects of nifedipine are described in only one publication with a randomized clinical trial of 10 participants and a open trial of 34 participants and therefore aren't very strong. As patients with perniones do have a need or effective treatment to

relieve them from their complaints and limitations we are of the opinion that it is useful investigate the possible effectiveness of nifedipine in more detail.

Objective of the study:

Research question: Does oral administration with regulated release of 60 mg nifedipine a day reduce the symptoms of
patients as determined in 1st. line health care, provided there is a good tolerancy of the medication.

Study design:

This research has been set up as an RCT of the cross over type. A group of 50 perniones patients is randomised over
two sub groups. After one week of baseline measurements withhout intervention, they are treated with nifedipine or a
placebo for 6 weeks in turns, blindfold to the patient and researcher. The duration of the research is 13 weeks for each patient. The most important confounder, exposure to cold, is monitored by asking for the twenty-four hours data of "de Bilt" at the Royal Duch Meteorological Institute KNMI and specific questions at intake.

Analysis:

A statistical analysis will be performed with a repeated measures mixed effects model. The effect of a possible change in temperature will be taken into account. An intention to treat analysis will take place. A check on the consistent use of the therapy will be done by counting forgotten tablets.

Power measurement:

In previous research we found baseline VAS scores for complaint of 27.97 millimeter (SD 18.82mm) on average. We regard the intervention effective when the VAS score has dropped by 10 millimeter or more. For the power measurement we took a paired T-test as a baseline. With one measurement per person for medication and placebo this is a considerable simplification of the real test. Repeated measurements allow less participants, which is more favourable. At alpha =0.05, beta=0.10 (power 90%) and an effect of 10mm VAS 38 patients are required to show a significant difference between the treatment with nifedipine and the placebo.

We do not expect major side effects.

Study objective

Oral administration with regulated release of 60 mg nifedipine a day will reduce the symptoms of patients suffering from complaints of chronic chilblains, as determined in 1st. line health care, provided there is a good tolerancy of the medication.

Study design

Regime 1:

1. 1 week no medication;

2. 2 weeks placebo once a day and 4 weeks placebo twice a day;

3. 2 weeks nifedipine 30 mg regulated release once a day and 4 weeks nifedipine 30 mg regulated release twice a day.

Regime 2:

1. 1 week no medication;

2. 2 weeks nifedipine 30 mg regulated release once a day and 4 weeks nifedipine 30 mg regulated release
twice a day;

3. 2 weeks placebo once a day and 4 weeks placebo twice a day.

The measuring instrument is a diary kept up to date daily by the participant for the complete research period. Experienced perniones complaints (itch or pain) and limitations in daily life are scored daily. For the complete research period of each individual patient the exposure to cold is registered by asking for the average day temperature as measured in "de Bilt" at the KNMI.

There are 6 contact moments: Intake (t1), end of week 1 (t2), end of week 3 (t3), end of week 7 (t4), end of week 9 (t5) and end of week 13 (t6).

Control and correction on the completeness of the diary and the consistency of the therapy used is performed by counting the tablets that are left. During controls at t2-t6 Blood pressure and pulsrate are monitored.

Intervention

The intervention which is compared to the placebo consists of the oral administration 30mg nifedipine with regulated
release once a day for two weeks and twice a day for four weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. 18 years of age or older;

2. Sufficient cognitive functioning and sufficient
command of the Dutch language to understand the instructions;

3. At inclusion the patient has experienced the following
for a minimum of three weeks:

A. Itching and/or painful blue purple discoloration on vingers and/or toes and/or places on the foot or on the outside of the thigh (the Kibes);

B. The first onset of the complaints was in the period from November to February;

C. There could be swelling and there could be ulcerae, but these are not obligatory.

Exclusion criteria

1. Known rheumatic disorders (RA, SLE, etcetera);

2. Pregnancy;

3. Breast-feeding;

4. Use of a corticosteroid cream;

5. Hypotension (pb < 110/60);

6. Angina pectoris;

7. Recent myocardial infarction (less than one month);

8. Heartfailure;

9. Known liver or kidney function disorder;

10. Severe gastrointestinal stricture;

11. Use of rifampicine, fenytoine, cimetidine or ranitidine.

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):	01-11-2010

Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	31-10-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34714
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2475
NTR-old	NTR2591
CCMO	NL31484.091.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34714

Study results

Summary results
1. Souwer IH, Lagro-Janssen ALM. Perniones. Winterhanden, Wintertenen en ‘Winterdijen’. HuisartsWet 2004;47:594-6.
2. Souwer IH, Lagro-Janssen ALM. De behandeling van perniones. Een literatuurstudie. Huisarts Wet 2004;47 (12):561-4.

3. I.H Souwer, L.J.H.Robins, A.L.M. Lagro-Janssen. Chilblains from the patient’s perspective. Eur J Gen Pract 2007;13:159-60.
4. Souwer IH, Lagro-Janssen ALM. Vitamin D3 is not effective in the treatment of chronic chilblains. Int J Clin Pract 2009;63:282-286.