Randomised controlled trial of the treatment of warts in general practice.

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The usual treatment for warts in Dutch general practice is cryotherapy with liquid nitrogen. More than 50% of all warts are treated with cryotherapy alone and in only 14% salicylic acid is used as mono-therapy. The prestigious Cochrane review...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26788

Bron
NTR

Verkorte titel
WARTS: WArts Randomized Treatment Study

Aandoening

Common (not genital) warts

Ondersteuning

Overige ondersteuning: Zon-MW Fonds Alledaagse Ziekten
PO box 93 245
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is defined as ‘cure', which means that the wart(s) have totally disappeared (normal skin) at 13 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

* objective(s) / research question(s):
Is treatment with cryotherapy more effective than treatment with salicylic acid and are both therapies more effective than an expectant awaiting policy (natural history)?
Are there subgroups (age, location, number of warts, previous self-treatment), which react differently on therapy?
* study design:
Randomised controlled trial in 32 GP practices
* study population(s)/ datasets:
Patients (all ages) contacting the general practice with warts.
* intervention:
Comparison of cryotherapy (2-week interval), salicylic acid therapy and an expectantly awaiting policy.
* outcome measures:
1) Cure rate (total disappearance observed by a blinded research nurse), 2) number of persisting warts,
subjective hindrance caused by warts and acceptability of therapy as scored by the patient, 3) adverse effects (including new warts) of the three approaches, 4) additional treatment during and after
intervention period (13 weeks). Follow-up moments at 4, 13 and 26 weeks
* power/data analysis:
Because of presumed less adverse effects and logistic and practical advantages salicylic acid is the preferential therapy when the cure rate for cryotherapy is not more than 20% higher than salicylic acid. .
With an alpha of 0.05 and a beta of 0.20 we need 71 patients in each group. When we estimate a loss to follow-up of 20% we need about 250 patients with new warts. With this number we can also detect a
difference of 20% between expectantly the awaiting policy and the active treatments.
* time schedule:
Months 1-6: development patient record form, recruitment of general practitioners and practice
assistants and instruction in uniform application of cryotherapy, instruction for ointment treatment.
Instruction of research nurses on protocol and on assessment of warts. Months 6-18: patient

inclusion, intervention, data collection. Months 18-24: data analysis and preparation of scientific reports.

Doel van het onderzoek

The usual treatment for warts in Dutch general practice is cryotherapy with liquid nitrogen. More than 50% of all warts are treated with cryotherapy alone and in only 14% salicylic acid is used as mono-therapy.
The prestigious Cochrane review concludes that there is an urgent need for high-quality randomised controlled trials on the routine treatments for common warts, particularly cryotherapy. While there is convincing evidence for the efficacy of topical salicylic acid compared to placebo,
high quality studies in which cryotherapy and salicylic acid compared to natural history are still lacking.
According to the Cochrane review the most urgent need is for a trial to compare topical salicylic acid, cryotherapy and placebo. Since the most recent amendment (May 2003) no new studies are published.

Onderzoeksproduct en/of interventie

Treatment arms
For the treatment with cryotherapy we chose for a high-intensity regimen: a 2-weekly consultation till the
wart has disappeared (until max. 13 weeks), 3 applications of the same wart per session, each application
until a frozen halo appears of 2 mm around it?s base.
For the local treatment with salicylic acid vaseline album (petrolatum) we use a once a day application of
a concentration of 40% for warts on the sole of the feet and on other parts of the skin. We choose for a
concentration of 40% to offer patients a stronger therapy than the over-the-counter therapies (like
Formule-W), which have a concentration of 17%. Covering the skin up with tape will protect the skin
around the wart. Application will be continued till the wart has disappeared (max. until 13 weeks).
Patients who were randomised into the natural history arm will be informed about the high spontaneous
cure rate. We refrained from a placebo-comparison because this insufficiently resembles daily practice.
An expectantly awaiting group will in the intervention period will reliably reflect patient behaviours,
including seeking of additional therapy (ability to maintain the expectantly awaiting policy).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients from the age of 4 onward, who present themselves to their practice with one or more new warts of the type vulgaris on hands or feet will be included? New warts are warts who are presented for the first time in the general practice by patients who have had no general practice (or dermatological) treatment for warts in the past year. For all patients duration of presence of the warts and the previous
treatment(s) will be registered.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are: immuno-incompetent patients and mosaic warts larger than 1 cm in diameter.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2006
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-09-2005
Soort:	Eerste indiening

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	NL379
NTR-old	NTR419
Ander register	: N/A
ISRCTN	ISRCTN42730629

Resultaten

Samenvatting resultaten
N/A