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WArts Randomised Treatment Study

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/01/2006	**Overall study status** Completed	
Last Edited 06/01/2014	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR419

Study information

Scientific Title

Randomised controlled trial of the treatment of warts in general practice

Acronym
WARTS

Study objectives
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 are 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre, randomised controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Warts (Verruca vulgaris)

Interventions
Treatment arms:
For the treatment with cryotherapy we chose a high-intensity regimen: a 2-weekly consultation

till the wart has disappeared (maximum 13 weeks), 3 applications of the same wart per session, each application until a frozen halo appears of 2 mm around its base.

For the local treatment with salicylic acid vaseline album (petrolatum) we used 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 chose 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 (maximum 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 reliably reflect patient behaviours, including seeking of additional therapy (ability to maintain the expectantly awaiting policy).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Salicylic acid

Primary outcome measure
Cure', meaning that the wart(s) have totally disappeared (normal skin) at 13 weeks.

Secondary outcome measures
1. The number of warts that still exist at follow-up, irrespective of the extent of regression (because for a separate wart regression cannot be validly assessed)
2. The subjective hindrance caused by the warts as scored by the patient on a numerical rating scale (0 - 10)
3. The subjective hindrance caused by the treatment as scored by the patient on a seven point scale (during the treatment period this will be scored weekly in a booklet)
4. Pain and other adverse effects of the treatments (pain, new warts, scars, irritation of the skin, dermatitis discomfort, invalidation, time)
5. Subjective judgement of the effect of the treatment by the patient at follow-up
6. Subjective judgement of the effect of the treatment by the research nurse at follow-up
7. Referral to a dermatological department, assessed at 26 weeks
8. After three months of the intervention period, patients for whom the warts have not disappeared are free to switch therapy. In the follow-up period we will carefully register to which therapies patients have switched and also if, and after how long this therapy leads to total disappearance of the warts.
9. The consumption of co-interventions during the intervention period and thereafter will also be used as secondary endpoints

Overall study start date
01/03/2006

Completion date

01/03/2008

Eligibility

Key inclusion criteria
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 which 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.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
250

Key exclusion criteria
Immuno-incompetent patients and mosaic warts larger than 1 cm in diameter.

Date of first enrolment
01/03/2006

Date of final enrolment
01/03/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre
Leiden
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Sponsor information

Organisation
Sponsor not yet defined (The Netherlands)

Sponsor details
-
-
Netherlands
-

Sponsor type
Not defined

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/10/2010		Yes	No
Results article	results	01/07/2013		Yes	No