WArts Randomised Treatment Study 2.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25205

Source
NTR

Brief title
WARTS-2

Health condition

Patients with hand- or plantar warts of the type vulgaris.

Sponsors and support

Primary sponsor: Prof. dr.WJJ Assendelft, head of department Public Health and Primary Care
Leiden University Medical Centre
Source(s) of monetary or material Support: The Dutch Organisation for Health Research and Development (ZonMw) (The Netherlands) Funding Daily diseases

Intervention

Outcome measures

Primary outcome

'Cure', meaning all common- and plantar wart(s) have totally disappeared (normal skin) at 13 weeks.

Secondary outcome

The number of warts that still exist at follow-up, the subjective hindrance caused by the warts as well as by the treatment, pain and other adverse effects of the treatment, subjective judgement of the effect of the treatment by the patient, objective judgement of the effect of the treatment by the research nurse at follow up, the consumption of co-interventions during follow-up.

Study description

Background summary

Warts are a common problem in general practice. Most often patients want warts to be treated due to pain or they find them ugly.
Results of WARTS-1 show a significant efficacy of cryotherapy for the treatment of common warts. Although still 1 out of 2 patients receive a painful treatment without being cured. For plantar warts none of the studied treatments showed better results than expectantly policy.
In WARTS-2 we will study the effect of the promising treatment with monochloroacetic acid compared to cryotherapy on common warts. In case of plantar warts we compare monochloroacetic acid with the combined treatment of salicylic acid and cryotherapy.
Using the results of WARTS-1 and WARTS-2 we aim to develop an evidence-based guideline for the treatment of common- and plantar warts.

Study objective

Results of WArts Randomised Treatment Study of 2006 show that the best treatment for common warts is cryotherapy compared to salicylic acid or awaiting policy (after 13 weeks). In case of plantar warts none of either treatments (cryotherapy or salicylic acid) is better than awaiting policy (30% cure rate after 13 weeks).
Pain is a common side effect of treatment with cryotherapy. Although cryotherapy is an effective treatment for common warts, still 1 out of 2 patients treated with cryotherapy receive a painful treatment without being cured.
Two small studies in dutch general practices show that monochloroacetic acid could be an effective alternative for the treatment of warts without painful side effects. Steele et al found higher cure rates for patients treated with the combination of monochloroacetic acid and local treatment with salicylic acid compared to patients treated with placebo. However convincing evidence of the efficacy of treatment with monochloroacetic acid as monotherapy is still lacking.

The combination of cryotherapy and local treatment with salicylic acid is commonly used in Dutch general practices, although evidence lacks. Since individual treatment of both salicylic acid and cryotherapy showed no better cure rates in plantar warts than awaiting policy, we chose to compare two possibly promising treatments: treatment with monochloroacetic acid and the combination therapy of salicylic acid and cryotherapy.

Study design

Assesment by a research nurse will take place at the start, 4 and 13 weeks after the patient has started with the treatment. The research nurse will visit patient at home. Warts will be examined and a questionnaire will be taken, which takes on average 30 minutes.

Intervention

Treatment arms:

Common warts:

Monochloroacetic acid: We chose to use a saturated concentration of 76% of monochloroacetic acid for application on a 2 weekly basis.

Cryotherapy: We chose a regimen of a 2-weekly consultation with 3 applications of the same wart per session. Both treatments will be continued until the wart has disappeared (maximum 13 weeks).

Plantar warts:

Monochloroacetic acid: We chose to use a saturated concentration of 76%of monochloroacetic acid for application on a 2 weekly basis.

Combination therapy (salicylic acid + cryotherapy): The patient will be instructed to first apply salicylic acid in vaseline album (petrolatum) 40% at home every evening on the sole of the feet for 2 weeks. Thereafter the patient visits the general practice for treatment with cryotherapy, 3 applications of the same wart per session. This regimen of combination of both therapies will be continued until the wart has disappeared (maximum 13 weeks).

Contacts

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Eligibility criteria

Inclusion criteria

All patients from the age of 4 onward, who present themselves to their general practitioner with one or more new warts of the type vulgaris on commons or feet.

Exclusion criteria

Immunocompromised patients, patients with mosaic warts larger than 1 cm in diameter, women who are pregnant or who are breastfeeding their children.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	400

Type:	Anticipated

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	NL1670
NTR-old	NTR1771
Other	ZonMW : 80-81000-98-099
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A