

Monochloroacetic acid versus cryotherapy or combination therapy in the treatment of warts: A Randomised Clinical Trial (WARTS-2)

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To assess the efficacy of treatment with monochloroacetic compared to treatment with cryotherapy regarding patients with handwarts and compared to combination therapy (salicylic acid and cryotherapy) regarding patients with plantar warts.WARTS-1 has...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON33146

Source

ToetsingOnline

Brief title

WARTS-2

Condition

- Viral infectious disorders
- Epidermal and dermal conditions

Synonym

verrucae vulgaris, warts

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: ZonMW Fonds Alledaagse Ziekten

Intervention

Keyword: cryotherapy, incidence, monochloroacetic acid, natural history, salicylic acid, Warts

Outcome measures

Primary outcome

*Cure', meaning all hand- or 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, referral to a dermatological department and the consumption of co-interventions during intervention period.

Study description

Background summary

WArts Randomised Treatment Study of 2006 compared treatment with salicylic acid to treatment with cryotherapy and both treatments to expectantly policy. Results show that the best treatment for hand warts is cryotherapy (cure rate 50%). In case of plantar warts neither treatment with salicylic acid nor with cryotherapy showed better results than awaiting policy (30% cure rates). Although cryotherapy is an effective treatment for hand warts, still 1 out of 2 patients treated with cryotherapy receives a painful treatment without being cured. Monochloroacetic could be an effective alternative without painful side

effects. However convincing evidence of the efficacy of this treatment is still missing. The combination of cryotherapy and local treatment with salicylic acid is commonly used in Dutch general practices for the treatment of plantar warts, although evidence concerning this treatment is also lacking.

Study objective

To assess the efficacy of treatment with monochloroacetic compared to treatment with cryotherapy regarding patients with handwarts and compared to combination therapy (salicylic acid and cryotherapy) regarding patients with plantar warts. WARTS-1 has provided answers on the main questions about treatment of warts in general practice. With the results of WARTS-1 and WARTS-2 altogether we aim to provide an evidence-based guideline regarding therapy for hand- or plantar warts in general practice.

Study design

Multicentre, randomised controlled parallel group trial in 80 general practices.

Intervention

Treatment of handwarts with either a saturated concentration of monochloroacetic acid 76% or with cryotherapy.

Treatment of plantar warts with either a saturated concentration of monochloroacetic acid 76% or with the combination therapy of salicylic acid 40% and cryotherapy.

Study burden and risks

Treatment of hand- and plantar warts with salicylic acid, cryotherapy and monochloroacetic acid are common treatments for warts in general practice. Therefore, by participating to this study there are no extra risks for patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

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 verruca vulgaris on hands or feet will be included.

New warts are warts which are presented for the first time in their general practice by patients who have had no general practice (or dermatological) treatment for warts in the past year.

Exclusion criteria

Immunocompromised patients

Patients with mosaic warts larger than 1 cm in diameter

Patients with warts who are pregnant or who are breastfeeding

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2009
Enrollment:	400
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	not applicable
Generic name:	monochloroacetic acid
Product type:	Medicine
Brand name:	not applicable
Generic name:	salicylic acid

Ethics review

Approved WMO	
Date:	10-06-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	06-08-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
EudraCT	EUCTR2009-012210-48-NL
CCMO	NL27534.058.09