

How effective is local treatment of Molluscum Contagiosum compared to watchful waiting?

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The aim of this study is to compare the effect of early treatment on healing and quality of life with the usual expectant policy in children with mollusca contagiosa.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON49061

Source

ToetsingOnline

Brief title

Mollusca trial

Condition

- Skin and subcutaneous tissue disorders NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym

Molluscum contagiosum or 'water warts'

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

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

Intervention

Keyword: Cryotherapy, Curettage, Local treatment, Molluscum contagiosum

Outcome measures

Primary outcome

The primary outcome measure is the difference in total healing (no mollusca present) after 26 weeks between the intervention and control groups.

Secondary outcome

Secondly, we will look at the differences between the groups with regard to, symptoms, the perceived quality of life, side effects of the treatments, subjective experience of the treatment undergone, the number and nature of possible co-interventions and possible transmission of mollusca within the family.

Study description

Background summary

Molluscum contagiosum or water warts is a common everyday disease that mainly affects children aged 1 to 14 years (prevalence 5-11%) [1]. It usually starts with a few lesions and can spread to a few dozen. In most cases, it takes more than a year for spontaneous healing to occur, but often longer [2]. For a significant proportion of patients, the condition has a significant negative effect on their quality of life, especially if there is a higher number of lesions and the lesions last longer [2].

In order to arrive at a well-considered choice whether to treat or not and to choose the most suitable treatment option, it is important to know how effective the different options are. Early intervention may have a positive effect on the course and complaints compared to waiting for spontaneous recovery. However, there is still insufficient evidence and none of the treatments has yet been demonstrated to be effective [3].

Study objective

The aim of this study is to compare the effect of early treatment on healing and quality of life with the usual expectant policy in children with mollusca contagiosa.

Study design

It is a prospective randomized study.

Intervention

The two most common interventions in the Netherlands, cryotherapy and curettage [3, 4], are compared with an expectant policy. The participants will be randomized at inclusion on three research arms with the same number of participants in each arm.

Study burden and risks

Cryotherapy and curettage are two limited invasive treatment methods that will therefore be performed according to the guideline [4] under local anesthesia using EMLA cream. EMLA cream is a proven effective surface anesthetic and is used to prevent possible pain during treatment as much as possible. In addition to any itching complaints as a result of the treatment, there is a small chance of complications, including wound infection, blistering and scarring. Any complications during or after treatment will be reported and, if necessary, treated additionally in accordance with the applicable guidelines. In addition, the test subject and parents or legal representative will be charged with the first (home) visit, the questionnaires to be administered and follow-up. Naturally, extensive verbal and written explanations will be given in advance as part of the informed consent procedure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Children (4 - 18 years old) with Molluscum contagiosum (maximum of 15 lesions)

Exclusion criteria

- Immunodeficient / immunocompromised children;
- Facial involvement and/or anogenital involvement;
- (Known) extreme fear of invasive medical procedures (such as curettage or cryotherapy);
- Recent (<1 year) treatment of molluscum contagiosum with one of the treatment modalities being investigated in this study, i.e. curettage and/or cryotherapy

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-01-2021
Enrollment: 99
Type: Anticipated

Ethics review

Approved WMO
Date: 11-12-2020
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20359
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL74903.058.20
OMON	NL-OMON20359