Local treatment of Molluscum Contagiosum in children

No registrations found.

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

Summary

ID

NL-OMON20359

Source
Nationaal Trial Register

Brief title
Mollusca trial

Health condition

Molluscum Contagiosum

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Fonds Alledaagse Ziekten

Intervention

Outcome measures

Primary outcome

Cure / clearance of mollusca contagiosa

Secondary outcome

Difference (percentage) in cure between the different study-arms

Occurence of side effects (such as peri-procedural and post-procedural pain, blistering, pruritus, infection, scar formation, pigment changes)

Study description

Background summary

Rationale: Molluscum contagiosum or water warts is a common everyday condition 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 resoluttion 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 an informed choice whether or not to treat 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].

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: This is a prospective randomized study.

Study population: Given the prevalence and treatment options to be investigated, this study focuses on patients 5 to 18 years of age with mollusca contagiosa with one to a maximum of five (?) Ten lesions [2].

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.

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

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 consent will be given in advance as part of the informed consent procedure.

Study objective

Intervention (cryotherapy OR curettage) will result in quicker resolution of the mollusca (i.e. no more lesions) and shorter duration of symptoms

Study design

Total treatment and follow-up of 6 months (intervention and/or check at baseline, 4, 8 and 26 weeks)

Intervention

Curettage or cryotherapy

Contacts

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Eligibility criteria

Inclusion criteria

Children (5 - 18 years old) with mollusca contagiosa (max 15 lesions)

Exclusion criteria

Immuundeficient / immunocompromised children; facial involvement; genital involvement; known extreme fear of invasive medical procedures (such as curettage or cryotherapy); recent (<1 year) treamtent of molluscum contagiosum with one of the treamtent molidaties of this study, being curettage and/or cryotherapy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	108
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 49061
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8804
CCMO	NL74903.058.20
OMON	NL-OMON49061

Study results