

Local treatment of Molluscum Contagiosum in children

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20359

Bron

NTR

Verkorte titel

Mollusca trial

Aandoening

Molluscum Contagiosum

Ondersteuning

Primaire sponsor: Leids Universitair Medisch Centrum

Overige ondersteuning: Fonds Alledaagse Ziekten

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cure / clearance of mollusca contagiosa

Toelichting onderzoek

Achtergrond van het onderzoek

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 resolution 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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Curettage or cryotherapy

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Immuundeficient / immunocompromised children; facial involvement; genital 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 of this study, being curettage and/or cryotherapy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	108
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49061

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten