

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Investigation of complete-response rate of intralesional immunotherapy with Candida antigen for the treatment of molluscum contagiosum

Protocol summary

Study aim

Determination of complete response rate of intralesional immunotherapy with candida antigens in the treatment of Molluscum contagiosum

Design

Clinical trial with no control group, single group, with no blinding, carried out on patients with Molluscum contagiosum

Settings and conduct

This study is conducted on 40 patients with Molluscum contagiosum referring to the Dermatology Clinic of Ghaem and Imam Reza Hospitals in Mashhad. Monthly immunotherapy continues for a maximum of 6 treatment sessions. The criteria of response to treatment are: full recovery, which means all molluscums have disappeared and no response, meaning that all molluscums have remained during the study. The relative response is considered when one or more lesions (but not all the lesions) have recovered.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Acquisition of patient and parents' consent
Exclusion criteria : Pregnant or lactating women, violation of initial safety conditions or iatrogenic disease, infection with HIV1, increased sensitivity to Candida antigen, reception of any treatment in relation to molluscum during the past month

Intervention groups

Patients with negative prick test are selected and intra dermal injection in the forearm is carried out with 0.1 cc of CANDIN. The appearance or non-appearance and the post-injection reaction rate after 48-72 hours are recorded. The intra lesional injection rate of Candida antigens is determined by the intra dermal reaction size. Monthly immunotherapy continues until the mucosal lesions completely disappear, or for molluscums with less or no-response, it is repeated up to a maximum of 6 sessions of treatment. Patients are evaluated at the beginning of the study and in each treatment period, and the number and level of molluscums are recorded.

Main outcome variables

Complete response, relative response and no-response to the treatment of lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180411039265N2**

Registration date: **2019-03-02, 1397/12/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-02, 1397/12/11**

Update count: **0**

Registration date

2019-03-02, 1397/12/11

Registrant information

Name

Naghmeh Zabolinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3858 3845

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-15, 1397/05/24

Expected recruitment end date

2019-12-15, 1398/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of complete-response rate of intralesional immunotherapy with Candida antigen for the treatment of molluscum contagiosum

Public title
Investigation of complete-response rate of intralesional immunotherapy with Candida antigen for the treatment of molluscum contagiosum

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 acquisition of patient and parents' consent
Exclusion criteria:
 Pregnant or lactating women Violation of initial safety conditions or iatrogenic decease Infection with HIV1 Increased sensitivity to Candida antigen Reception of any treatment in relation to molluscum during the past month

Age
No age limit

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2018-05-09, 1397/02/19

Ethics committee reference number
IR.MUMS.fm.REC.1397.106

Health conditions studied

1

Description of health condition studied

Molluscum contagiosum

ICD-10 code

B08.1

ICD-10 code description

Molluscum contagiosum

Primary outcomes

1

Description

Complete-response, relative-response or no-response to the treatment of lesions

Timepoint

Monthly immunotherapy continues until the mucosal lesions completely disappear and for molluscums with less or no-response, it continues for a maximum of 6 treatment sessions.

Method of measurement

Number and level of molluscums are written down.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Firstly, scratch test (prick test) with Candida antigen is performed on all patients in order to determine the level of type 1 hypersensitivity to Candida. Patients with negative prick test are selected to reduce the risk of anaphylaxis and then intra dermal injection in forearm is carried out with one tenth of a cc (0.1 cc) of one of the Candida antigen derivatives called CANDIN, which is a cellular immune stimulant. The appearance or non-appearance and the post-injection reaction rate after 48-72 hours are recorded. Positive reaction confirmation requires redness and stiffening for at least 5 mm diameter. The intra lesional injection rate of Candida antigens is determined by the intra dermal reaction size and is as follows : injection of 0.3 cc in the case of stiffening (induration) with 5-20 mm diameter, 0.2 cc injection in case of stiffening with 20-40 mm diameter, 0.1 cc injection in case of stiffening with more

than 40 mm diameter. In case of a large lesion, it is possible to inject all the required volume inside it. But if there are only small lesions, there is a need for injection in 3 lesions to reach the full volume. Monthly immunotherapy continues until the mucosal lesions completely disappear, or for molluscums with less or no-response, it is repeated up to a maximum of 6 sessions of therapy. Patients are evaluated at the beginning of the study and in each treatment period, and the number and level of molluscums are recorded. During follow-up, response or non-response to treatment and reduction of the number of molluscums in the case of relative response to treatment are recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Saman Afkhami Ardakani

Street address

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2

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Naghme Zabolinejad

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Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saman Afkhami Ardakani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments