

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of topical sodium chlorite (NaClO₂) on the treatment course of lupoid leishmaniasis: A clinical trial

Protocol summary

Study aim

Effect of topical sodium chlorite (NaClO₂) on the treatment course of lupoid leishmaniasis: A clinical trial

Design

This clinical trial with a before and after treatment design of 20 patients with lupoid leishmaniasis were assigned base on community-based setting.

Settings and conduct

The study population will be selected from the patients with lupoid leishmaniasis referring to Imam Reza Hospital, Mashhad, Iran, and will be administered topical sodium chlorosome for treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of a history of positive smear for leishman body or pathology; clinical features associated with lesion of lupoid leishmaniasis. Exclusion criteria: Using alternative treatments 2 months prior or during the intervention, pregnancy or breastfeeding.

Intervention groups

The intervention group were subjected to topical sodium chlorosome (including 12 mM NaClO₂ with 10-11 PH and 2.4% glycerol with brand name of Oxoferin) twice a day for 6 weeks.

Main outcome variables

The evaluation and comparison of the therapeutic responses based on the photos taken of lesion before and 6 weeks after the treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190114042356N1**

Registration date: **2019-02-02, 1397/11/13**

Registration timing: **prospective**

Last update: **2019-02-02, 1397/11/13**

Update count: **0**

Registration date

2019-02-02, 1397/11/13

Registrant information

Name

Vahid Mashayekhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3606 5215

Email address

mashayekhiv1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical sodium chlorite (NaClO₂) on the treatment course of lupoid leishmaniasis: A clinical trial

Public title

The treatment of patients with lupoid leishmaniasis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

History of a history of positive smear for leishman body or pathology Clinical features associated with lesion of

lupoid leishmaniasis
Exclusion criteria:
 Using alternative treatments 2 months prior or during the intervention Pregnancy or breastfeeding

Age
 No age limit

Gender
 Both

Phase
 2

Groups that have been masked
 No information

Sample size
 Target sample size: 20

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

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2015-08-15, 1394/05/24

Ethics committee reference number

IR.MUMS.REC.1394.357

Health conditions studied

1

Description of health condition studied

Lupoid leishmaniasis

ICD-10 code

B55.9

ICD-10 code description

Leishmaniasis, unspecified

Primary outcomes

1

Description

Therapeutic responses

Timepoint

before and 6 weeks after the treatment

Method of measurement

The photos taken of lesion

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group were subjected to topical sodium chlorosome (including 12 mM NaClO₂ with 10-11 PH and 2.4% glycerol with brand name of Oxoferin) twice a day for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Vahid Mashayekhi

Street address

Imam Reza Hospital, Imam Reza Square, Mashhad

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Postal code

9137913316

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Email

mashayekhiv@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
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913753459

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vcresearch@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

Vahid Mashayekhi

Position

Associate Professor

Latest degree

Specialist

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

Vahid Mashayekhi

Position

Associate Professor

Latest degree

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

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Mashayekhi

Position

Associate Professor

Latest degree

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Email

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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

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Vahid Mashayekhi provides the analysis code to the applicants via email: mashayekhiv@mums.ac.ir

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

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments