

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Effect of topical sodium chlorite (NaClO<sub>2</sub>) on the treatment course of lupoid leishmaniasis: A clinical trial

#### Protocol summary

##### Study aim

Effect of topical sodium chlorite (NaClO<sub>2</sub>) 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 NaClO<sub>2</sub> 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 (NaClO<sub>2</sub>) 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 NaClO<sub>2</sub> 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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3606 5215

**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  
Street

**City**

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**Province**

Razavi Khorasan

**Postal code**

913753459

**Phone**

+98 51 3841 1538

**Email**

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

**Street address**

Imam Reza Hospital, Imam Reza Square, Mashhad

**City**

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**Province**

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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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**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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**Other areas of specialty/work**

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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**