

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **A comparative study of the effects of intralesional Meglumine Antimonate injection alone and intralesional Meglumine Antimonate injection plus local barberry root extract on improvement of skin lesions of patients with cutaneous leishmaniasis**

#### **Protocol summary**

##### **Summary**

This study compared the effects of intralesional Meglumine Antimonate injection alone and intralesional Meglumine Antimonate injection plus local barberry root extract on improvement of skin lesions of patients with cutaneous leishmaniasis. Major inclusion criteria comprised of positive direct smear in terms of Leishman-Donovan body and time passed less than 6 months from treatment onset. Major exclusion criterion consisted of allergy to Meglumine (severe local reactions or anaphylaxis) or topical compounds used. The study was double-blind, one-centered, and prospective. The patients were allocated into case group (20 patients and 27 lesions) and control group (20 patients with 29 lesions) via randomized blocked allocation method (i.e., 1:1). The cases received weekly intralesional Meglumine Antimonate injection plus 10% barberry root extract cream three times a day for 8 consecutive weeks. The controls received weekly intralesional Meglumine Antimonate injection plus placebo for 8 consecutive weeks. Clinical response in both groups was assessed in the last session of injection and 6 weeks after the last injection. The primary outcome to be evaluated was induration for which full recovery was defined as 100% or complete ulcerous re-epithelialization; significant recovery as reduced size of induration to over 75%; moderate recovery as reduced size of induration between 51% to 75%; partial recovery as reduced size of induration between 26% to 50%; and non-response as reduced size of induration less than or equal to 25%.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT2017060117756N16**

Registration date: **2017-06-02, 1396/03/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### **Registration date**

2017-06-02, 1396/03/12

##### **Registrant information**

###### **Name**

Mohammad Bagher Roozgar

###### **Name of organization / entity**

Birjand University of Medical Sciences

###### **Country**

Iran (Islamic Republic of)

###### **Phone**

+98 56 3239 5680

###### **Email address**

mbroozgar@bums.ac.ir

##### **Recruitment status**

###### **Recruitment complete**

##### **Funding source**

Vice-chancellery for Research of Mashhad University of Medical Sciences

##### **Expected recruitment start date**

2013-03-21, 1392/01/01

##### **Expected recruitment end date**

2014-03-20, 1392/12/29

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

##### **Scientific title**

A comparative study of the effects of intralesional Meglumine Antimonate injection alone and intralesional Meglumine Antimonate injection plus local barberry root extract on improvement of skin lesions of patients with cutaneous leishmaniasis

#### Public title

Comparing the effects of intralesional Meglumine Antimonate injection alone and intralesional Meglumine Antimonate injection plus local barberry root extract in cutaneous leishmaniasis treatment

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Positive direct smear in terms of Leishman-Donovan body; time passed less than 6 months from legion onset; no other treatment received for leishmaniasis during the last three months; informed consent for participation; lesion located is in upper limbs or the face. Exclusion criteria: Allergy to Meglumine (severe local reactions or anaphylaxis) or topical compounds used; irregular visits; incidence of secondary infection of the lesions based on clinical features and the therapist's judgment ; presence of systemic treatment indications for cutaneous leishmaniasis including lesions on joints, number of lesions more than or equal to 5, lesion size more than or equal to 5 cm.

#### Age

No age limit

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

No information

#### Sample size

Target sample size: 40

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### 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-chancellery for Research, Mashhad University of Medical Sciences, Daneshgah Ave.,

#### City

Mashhad

#### Postal code

#### Approval date

2012-10-13, 1391/07/22

#### Ethics committee reference number

IR.mums.rec.1390.13

### Health conditions studied

#### 1

##### Description of health condition studied

cutaneous leishmaniasis

##### ICD-10 code

B55.1

##### ICD-10 code description

Cutaneous leishmaniasis

### Primary outcomes

#### 1

##### Description

Enduration

##### Timepoint

On the last injection and 6 weeks later

##### Method of measurement

ruler

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention Group: The cases received weekly intralesional Meglumine Antimonate injection plus 10% barberry root extract cream three times a day for 8 consecutive weeks.

##### Category

Treatment - Drugs

#### 2

##### Description

Control Group: The controls received weekly intralesional Meglumine Antimonate injection plus placebo for 8 consecutive weeks.

##### Category

Treatment - Drugs

### Recruitment centers

1

**Recruitment center**

**Name of recruitment center**

Leishmaniasis Research Center

**Full name of responsible person**

Dr. Mehdi Razmara Farzaghi

**Street address**

Leishmaniasis Research Center, Ghaem Hospital,  
Koohsangi Ave.

**City**

Mashhad,

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice-chancellery for Research of Mashhad University  
of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Vice-chancellery of Research and Technology,  
Mashhad University of Medical Sciences, Daneshgah  
Ave.,

**City**

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice-chancellery for Research of Mashhad University of  
Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mehdi Razmara Farzaghi

**Position**

Doctor of Medicine

**Other areas of specialty/work**

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Imam Reza Hospital

**Full name of responsible person**

Dr Masoud Maleki

**Position**

Dermatologist

**Other areas of specialty/work**

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**Name of organization / entity**

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**Full name of responsible person**

Mohammad Bagher Roozgar

**Position**

PhD Candidate in Translation Studies

**Other areas of specialty/work**

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**Web page address**

**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*