

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

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Iran (Islamic Republic of)

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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

Mashhad

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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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Imam Reza Hospital

Full name of responsible person

Dr Masoud Maleki

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Dermatologist

Other areas of specialty/work

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Position

PhD Candidate in Translation Studies

Other areas of specialty/work

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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