Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Mohammad Bagher Roozgar

Name of organization / entity

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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 leishmaniosis 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 leishmaniosis 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 Reasearch, 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 Medicla Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Vice-chancellery of Reasearch 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 Medicla 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
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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