Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of intralesional amphotericin B for treatment of cutaneous leishmaniasis in patient referred to Dermatology Clinic of Imam Reza Hospital

Protocol summary

Summary

This study aims to evaluate efficacy of intra-lesional injection of Amphotricin B in the treatment of Antimoniate resistant or intolerant cutaneous leishmaniasis cases. Leishmaniasis patients whose clinical diagnosis has been confirmed by Gimsa stained slit skin smears and are candidate for local treatment modalities, but are unresponsive to intralesional injections of glucantim, or are unable to continue their treatments because of allergic reactions, undergo weekly intralesional injections of 1.5-2mg/dl of Amphotricin B. The standard trial is up to 12 weeks but in case of complete clinical responses the therapy will be stopped before this deadline and for therapy resistant cases it will be continued up to 6 months. Treatment result is defined as reduction in the size and induration of the leisions, and at the end of the trial will be categorized as: complete resolution (full evanescence of inflammation and indurations), Partial improvement (70-90 percent reduction in inflammation and indurations), and no response (less than 70 percent reduction in inflammation and indurations). Also, the patients will be followed up for recurrences up to a year.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105223862N7**
Registration date: **2011-11-20, 1390/08/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-11-20, 1390/08/29

Registrant information

Name

Farahzad Jababri Azad

Name of organization / entity

Mashahd University of Medical Scineces

Country

Iran (Islamic Republic of)

Phone

+98 51 1843 6626

Email address

banihashemim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2008-09-01, 1387/06/11

Expected recruitment end date

2011-08-31, 1390/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of intralesional amphotericin B for treatment of cutaneous leishmaniasis in patient referred to Dermatology Clinic of Imam Reza Hospital

Public title

to evaluate the efficacy of amphotericin B injection in trearment of cutaneous leishmaniasis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: diagnosis of Cl based on direct skin smear or biopsy, lesion number less than 4, hypersensitivity to Antimoniate, resistance to Antimoniate therapy, informed consent signing Exclusion criteria: hypersensitivity to amphotricin

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

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
Central Building of Mashhad University of Medical Sciences, Mashhad.

City
Mashhad

Postal code

Approval date
2007-06-24, 1386/04/03

Ethics committee reference number
2069

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
lesion healing

Timepoint
weekly

Method of measurement
measuring the size of induration and ulcer by caliper

Secondary outcomes

1

Description
side effect

Timepoint
weekly

Method of measurement
clinical evaluation

Intervention groups

1

Description
intralesional injection of Amphotricin, once weekly for 6-12 week.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Research center for skin diseases and cutaneous leishmaniasis

Full name of responsible person
Dr vahid Mashayekhi

Street address
Dermatology department, Imam reza hospital, avicenna street.

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research council of mashhad University of Medical Sciences.

Full name of responsible person
Vice chancellor for research

Street address
central building of Mashhad University of Medical Sciences

City
mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research council 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
Research center for skin diseases and cutaneous leishmaniasis
Full name of responsible person
Dr Vahid Mashayekhi
Position
Dermatopatologist
Other areas of specialty/work
Street address
Department of dermatology, Imam Reza hospital, Avicennia street
City
Mashhad
Postal code
Phone
+98 51 1802 2490
Fax
Email
mashayekhiv@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of dermatology, Imam Reza hospital, Mashhad University of Medical Sciences
Full name of responsible person
Dr Vahid Mashayekhi
Position
Assistant professor of dermatology
Other areas of specialty/work
Street address
Department of dermatology, Imam Reza hospital, Avicenna street, Imam Reza square
City
Mashhad
Postal code
Phone
+98 51 1802 2490
Fax
Email
mashayekhiv@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Research center for skin diseases and cutaneous leishmaniasis
Full name of responsible person
Akram sadat Momenzadeh
Position
bachelor of sciences, biologist
Other areas of specialty/work
Street address
Research center for skin diseases and cutaneous leishmaniasis,office bulding, Ahmad abad street, Ghaem hospital.
City
mashhad
Postal code
Phone
+98 51 1841 0135
Fax
Email
src@mums.ac.ir
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