

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Antimoniote 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 lesions, 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

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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 treatment of cutaneous leishmaniasis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: diagnosis of CI 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

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Department of dermatology, Imam Reza hospital, Avicennia street

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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

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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

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Research center for skin diseases and cutaneous leishmaniasis,office bulding, Ahmad abad street, Ghaem hospital.

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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