

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy of Topical Liposomal Azithromycin versus Intralesional Meglumine Antimoniate (Glucantime) in the Treatment of Cutaneous Leishmaniasis

Protocol summary

Summary

This study conducted to compare the therapeutic effects of topical liposomal Azithromycin with interalesional Meglumine Antimoniate (Glucantime) in cutaneous leishmaniasis patients referring to cutaneous leishmaniasis clinic of Ghaem Hospital. In this study 66 patients with approved cutaneous leishmaniasis will enrolled to study. The first group (26 patients) will receive topical liposomal Azithromycin with 40 mg/ml twice daily for 8 weeks. The second group will receive interalesional glucantime weekly that would be infiltrated up to a maximum dose of 2 ml or until it would be paled up to lateral margins of the lesions, for 8 weeks. The results will be evaluated on changes in the size of induration of the lesion weekly. Patient's follow up will be done 6 months and 1 year after treatment. Response rate will determine by measuring the indurations as below: 1. complete improvement (full re-epithelialization of the lesions with or without a negative direct smear result). 2. Significant improvement: decrease in the indurations size >75%. 3. Partial improvement: decrease in the indurations size between 50%-75%. 4. Slight improvement: decrease in the indurations size between 25%-50%. 5. No improvement: decrease in the indurations size <25%.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901312082N2**
Registration date: **2010-04-20, 1389/01/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-04-20, 1389/01/31

Registrant information

Name

Amirali Rahsepar

Name of organization / entity

Mashad University of Medical science

Country

Iran (Islamic Republic of)

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+98 51 1604 2497

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rahseparaa841@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2009-12-24, 1388/10/03

Expected recruitment end date

2012-04-29, 1391/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Topical Liposomal Azithromycin versus Intralesional Meglumine Antimoniate (Glucantime) in the Treatment of Cutaneous Leishmaniasis

Public title

Comparing efficacy of two treatment methods including topical liposomal Azithromycin versus intralesional Meglumine Antimoniate (Glucantime) in the treatment of

cutaneous Leishmaniasis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: cutaneous leishmaniasis with less than 6 months duration approved by either a Giemsa direct skin smear or a positive skin biopsy of lesions, more than 3 month withdrawal from previous history of anti-leishmania therapy. Exclusion criteria: Pregnancy, breast feeding, taking any other specific treatment while participating in the study, past medical history of any systemic disease during the last 2 months, presence of known disease such as cardiac, renal or liver failure.

Age
From **2 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ehtical Committee of Mashhad University of Medical Sciences

Street address
Central Building of Mashad University of Medical Sciences

City
Mashhad

Postal code

Approval date
2009-12-22, 1388/10/01

Ethics committee reference number
86724

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
complete healing

Timepoint
Every two weeks up to 8 weeks and then once again after 6 months and 1 year after completing the interventions

Method of measurement
measuring the size of lesion induration diameter with caliper

Secondary outcomes

1

Description
Side effects

Timepoint
Every two weeks till 8 weeks

Method of measurement
Base on taking history and physical examination

Intervention groups

1

Description
Treatment with multilamellar Large Vesicle (MLV) liposomes containing Azithromycin, prepared by freeze drying method, 40 mg/ml twice-daily, according to the lesion's size for 8 weeks or complete healing of the lesion.

Category
Treatment - Drugs

2

Description
Treatment with interalesional meglumine antimoniate (glucantime) injection (1-2 ml) weekly untill 8 weeks or complete healing of the leishmaniasis

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Clinic of Cutaneous Leishmaniasis, Research center
for skin disease and cutaneous leishmaniasis

Full name of responsible person

Dr Pouran Layegh, Dr Mohsen Khodami

Street address

Ghaem Hospital, Ahmad Abad Street

City

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Fax

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hadis_yousefzadeh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Dermatology Department, Ghaem Hospital, Mashhad
University of Medical Sciences

Full name of responsible person

Dr Pouran Layegh

Position

Associate professor of Dermatology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Research center of skin disease and cutaneous
leishmaniasis

Full name of responsible person

Hadis Yousefzadeh

Position

Master of Sciences

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Mashhad University of Medical
Sciences

Full name of responsible person

Dr Jalil Tavakoli Afshari

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 disease and cutaneous
leishmaniasis

Full name of responsible person

Hadis Yousefzadeh

Position

Master of sciences

Other areas of specialty/work

Street address

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Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty