

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

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

Protocol summary

Summary

This study is designed to compare the therapeutic effects of a formulation of topical liposomal Amphotericin B with intralesional Meglumine Antimoniate (Glucantime) in the treatment of cutaneous Leishmaniasis due to *Leishmania Tropica*. 110 patients (55 patients in each group) with cutaneous leishmaniasis approved by either a direct smear stained with Giemsa or a positive skin biopsy of lesions with less than 6 months duration were enrolled in a randomized, single-blind controlled trial done during a 24-month period in Mashhad. The first group received liposomal Amphotericin B, 3-7 drops twice daily, according to the size of lesion, for 8 weeks. The second group received intralesional glucantime once a week, to the point when the surface of lesion became fully infiltrated (up to a maximum dose of 2 ml for 8 weeks). The treatment period was 8 weeks for each group and the patients are followed up every two weeks during the treatment course and the changes in the size of lesion and induration were recorded in every session. The primary outcome measure was complete healing of cutaneous leishmaniasis lesion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802131871N1**
Registration date: **2009-09-26, 1388/07/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-09-26, 1388/07/04

Registrant information

Name

Pouran Layegh

Name of organization / entity

Department of Dermatology, Qaem Hospital, Mashad
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical
Sciences

Expected recruitment start date

2004-09-10, 1383/06/20

Expected recruitment end date

2006-09-10, 1385/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Comparing efficacy of two treatment methods including
topical liposomal Amphotericin B versus intralesional
Meglumine Antimoniate (Glucantime) in the Treatment of
Cutaneous Leishmaniasis

Purpose

Treatment

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

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: **110**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics Committee of Mashad University of Medical Sciences

Street address
 Central Building of Mashad University of Medical Sciences, Mashad, Iran

City
 Mashad

Postal code

Approval date
 2004-08-10, 1383/05/20

Ethics committee reference number
 1803-ت

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
 First time within 8 weeks after beginning of treatment and second one after 6 months after initiation of the intervention(s)

Method of measurement
 Measuring the size of induration and ulcer

Secondary outcomes

1

Description
 Adverse Effects

Timepoint
 Recorded at each follow-up visit

Method of measurement
 Taking medical history and performing physical examination

Intervention groups

1

Description
 Multilamellar Large Vesicle (MLV) liposomes containing Amphotricin B, prepared by freeze drying method, 3-7 drops twice-daily, according to the lesion's size for 8 weeks or complete healing of the lesion.

Category
 Treatment - Drugs

2

Description
 Intralesional glucantime (Specia®, France) once a week, to the point when the lesion's surface became fully infiltrated, up to a maximum dose of 2 ml for 8 weeks

Category
 Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
 Clinic of Cutaneous Leishmaniasis, Research Center of

Skin Disease and Cutaneous leishmaniasis, Qaem

Full name of responsible person

Dr Poura Layegh, Dr Parisa Emamgholi -Tabar
Malekshah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Mashhad University of Medical
Sciences

Full name of responsible person

Research Council of Mashhad University of Medical
Sciences

Street address

Central Building of Mashhad University of Medical
Sciences, Mashad, Iran

City

Mashad

Grant name

Grant code / Reference number

1803-ت

**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

Department of Dermatology, Qaem Hospital, Mashad
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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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