# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 Amphotricin B with intralesional Meglumine Antimoniate (Gllucantime) 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 leismaniasis 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

**Country**

Iran (Islamic Republic of)

**Phone**

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**Email address**

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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

**Street address**

Qaem Hospital, Ahmad Abad Avenu

**City**

Mashad

## 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 Mashad 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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*