

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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, Mashhad  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1881 4988

##### Email address

layeghpo@mums.ac.ir

##### 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-ع

## **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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Qaem Hospital, Ahmad Abad Avenu

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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-ع

**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 Poursan Layegh

**Position**

Associate Professor of Dermatology

**Other areas of specialty/work**

**Street address**

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

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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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*