

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

2010-04-20, 1389/01/31

#### 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

#### Registrant information

##### Name

Amirali Rahsepar

##### Name of organization / entity

Mashad University of Medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1604 2497

##### Email address

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 Mashhad 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**

Mashhad

+98 51 1841 0135

**Fax**

**Email**

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**

**Street address**

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Mashhad University of Medical Sciences

**City**

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**Postal code**

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**Fax**

**Email**

layeghpo@mums.ac.ir

**Web page address**

**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**

Research center for skin disease and cutaneous  
leishmaniasis, Ghaem Hospital, Ahmad abad ave

**City**

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**Postal code**

**Phone**

**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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hadis\_yousefzadeh@yahoo.com

**Web page address**

**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*