

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing improvement of lesions in leishmaniasis patients with two treatment methods including trichloroacetic Acid (TCA) and interalesional meglumine antimoniate (Glucantime) for the treatment of Lupoid leishmaniasis

#### Protocol summary

##### Summary

The aim of this study is to compare combined intra-lesional injection of Glucantime and topical application of aqueous solution of trichloroacetic Acid (TCA) 50% in the treatment of cutaneous leishmaniasis. A total of 120 patients who their cutaneous leishmaniasis will be diagnosed by direct skin smear via Giemsa method or dermal biopsy and their clinical lesion course is less than 6 months will be recruited to receive interalesional glucantime (until the lesions are completely indurated to 1 mm of their surrounding area) or topical solution of TCA until the lesion is frosted for 8 weeks. The changes of lesion indurations in every follow up visit will be measured as primary outcome measure. Patients will be followed up for 3 months after the final therapeutic course and lesion indurations and possible side effects will be evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201101313862N6**

Registration date: **2011-04-11, 1390/01/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-04-11, 1390/01/22

##### Registrant information

###### Name

Farahzad Jababri Azad

###### Name of organization / entity

Mashahd University of Medical Scineces

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1843 6626

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###### Recruitment status

**Recruitment complete**

###### Funding source

Funded by Research Council of Mashhad University of Medical Sciences

###### Expected recruitment start date

2009-11-26, 1388/09/05

###### Expected recruitment end date

2011-08-27, 1390/06/05

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparing improvement of lesions in leishmaniasis patients with two treatment methods including trichloroacetic Acid (TCA) and interalesional meglumine antimoniate (Glucantime) for the treatment of Lupoid leishmaniasis

###### Public title

Comparing improvement of lesions in leishmaniasis patients with two treatment methods including trichloroacetic Acid (TCA) and interalesional meglumine antimoniate (Glucantime) for the treatment of Lupoid leishmaniasis

###### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: presence of cutaneous leishmaniasis in less than 6 months prior to the study that their disease has been approved by direct smear and stained with Giemsa or positive dermal biopsy, 3-month treatment-free interval from the last treatment course Exclusion criteria: pregnancy, breast-feeding, any administration of any other medication during the study that has anti-leishmaniasis ingredient during 2 last months, history of severe renal impairment, pulmonary and cardiovascular disease

### **Age**

To **80 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **120**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

##### **Street address**

Central building of Mashhad University of Medical Sciences

##### **City**

Mashhad

##### **Postal code**

86721

#### **Approval date**

2009-09-27, 1388/07/05

#### **Ethics committee reference number**

86721

## **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 at 8th weeks after treatment and the second time in follow up visit after 3 months of commencement of the study

#### **Method of measurement**

Measuring the width and induration and ulcer size

## **Secondary outcomes**

### **1**

#### **Description**

side effects

#### **Timepoint**

at each follow up visit

#### **Method of measurement**

Physical examination

## **Intervention groups**

### **1**

#### **Description**

Interalesional Glucantime injection, until the lesion with 1 mm of its surrounding is completely infiltrated, in size basis until the lesion is completely infiltrated and indurated, weekly up to 8 weeks

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Topical TCA 50%, after the lesion is frosted, the lesion site without washing is covered with topical cream, weekly until improvement time and will repeat up to 8 weeks

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Research Center of Skin Disease and Cutaneous

leishmaniasis, Ghaem Hospital  
**Full name of responsible person**  
Dr Mahnaz Banihashemi  
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Ghaem Hospital, Ahmad Abad Street  
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src@mums.ac.ir  
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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**  
Vice chancellor for research of Mashhad University of Medical Sciences, Dr Jalil Tavakol 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**  
Hasan Amir Soleimani  
**Position**  
General Practitioner

#### Other areas of specialty/work

**Street address**  
Research center of skin diseases and leishmaniasis, Office building, Ghaem Hospital, Ahmad Abad Street

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#### Phone

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Department of Dermatology, Ghaem Hospital, Mashad University of Medical Sciences  
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Dr Mahnaz Banihashemi  
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Associate Professor of Dermatology  
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## Person responsible for updating data

#### Contact

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Zamen Salamati Institute of healthcare services  
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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*