

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparing efficacy of combined cryotherapy and interalesional meglumine antimoniate (Glucantime) vs. cryotherapy and interalesional meglumine antimoniate alone for the treatment of cutaneous leishmaniasis

#### Protocol summary

##### Summary

The aim of this study is comparison of three methods including combined cryotherapy and interalesional Glucantime vs. cryotherapy and interalesional Glucantime alone for treatment of cutaneous leishmaniasis. 180 patients (3 groups with 60 patients) who their cutaneous leishmaniasis will be diagnosed by direct skin smear via Giemsa method or skin biopsy and their clinical lesion course have longed below 6 months will enter to study. The first group is treated with cryotherapy 10-20 s, until the lesion with 1 mm of its surrounding is completely indurated, and after 5 minutes interalesional Glucantime injection into the lesion, in size basis, weekly up to 8 weeks. The second group will be treated by cryotherapy 10- 20 s weekly until the lesion with 1 mm of its surrounding is completely indurated. The third group will be treated with interalesional glucantime injection into the lesion up to 8 weeks. Results will be recorded as the changes of lesion indurations in each follow up visit. Patients will be followed up 3 months after the end of treatment and lesion indurations and possible side effects will be recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903063862N4**

Registration date: **2010-05-27, 1389/03/06**

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

Last update:

Update count: **0**

**Registration date**

2010-05-27, 1389/03/06

##### 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

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Research Council of Mashhad University of Medical Sciences

##### Expected recruitment start date

2008-11-10, 1387/08/20

##### Expected recruitment end date

2010-07-21, 1389/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing efficacy of combined cryotherapy and interalesional meglumine antimoniate (Glucantime) vs. cryotherapy and interalesional meglumine antimoniate alone for the treatment of cutaneous leishmaniasis

##### Public title

Comparing improvement efficacy of leishmaniasis

patients with three treatment methods including combined cryotherapy and interalesional meglumine antimoniate (Glucantime) vs. cryotherapy and interalesional glucantime alone for the treatment of cutaneous leishmaniasis

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: presence of cutaneous leishmaniasis less than 6 months that their disease has been approved by direct smear and stained with Giemsa or positive skin biopsy, a 3-month treatment free interval from the last treatment course. Exclusion criteria: pregnancy, lactating, receiving simultaneously any therapy during study period that has antileishmaniasis effect during 2 months ago, history of significant renal, pulmonary and cardiovascular disease.

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

2-3

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

No information

#### **Sample size**

Target sample size: 180

#### **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**

Ethics Committee of Mashhad University of Medical Sciences

###### **Street address**

Central building of Mashhad University of Medical Sciences

###### **City**

Mashhad

###### **Postal code**

##### **Approval date**

2007-05-26, 1386/03/05

##### **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**

For the first time 6th and 8th weeks after treatment and for the second time in follow up visit after 3 months of beginning the study

##### **Method of measurement**

Measuring the size of induration and ulcer

### **Secondary outcomes**

#### **1**

##### **Description**

side effects

##### **Timepoint**

at each follow up visit

##### **Method of measurement**

Physical exam

### **Intervention groups**

#### **1**

##### **Description**

Treatment with cryotherapy 10-20 s, until the lesion with 1 mm of its surrounding is completely infiltrated, and after 5 minutes, interalesional Glucantime injection into lesion, in size basis, weekly up to 8 weeks

##### **Category**

Treatment - Other

#### **2**

##### **Description**

Treatment with cryotherapy 10-20 s, until the lesion and 1 mm of its surrounding is completely infiltrated, weekly up to 8 weeks

##### **Category**

Treatment - Other

#### **3**

##### **Description**

Interalesional Gluantime injection into lesion, in size basis, until the lesion is completely infiltrated and indurated, weekly 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, Dr fateme Shirzad

**Street address**

Ahmad Abad Street, Ghaem Hospital

**City**

Mashhad

**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**

Hadis Yousefzadeh

**Position**

Master of Sciences, Biologist

**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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**Postal code****Phone**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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

**Full name of responsible person**

Dr Mahnaz Banihashemi

**Position**

Associate Professor of Dermatology

**Other areas of specialty/work****Street address**

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**City**

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**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*