

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of therapeutic response to systemic Meglumine antimoniate (Glucantime) in children with acute Cutaneous Leishmaniasis comparing with adult patients

#### Protocol summary

##### Summary

A clinical trial which was performed during 12 months period on cutaneous leishmaniasis (CL) affected patients who visited the dermatology clinics of Qaem and Imama reza hospital and Villa's health center in Mashad-Iran. The parasitological diagnosis confirmed using Geimsa-stained direct smear and treatment was performed on an out-patient basis. To minimize the possibility of natural self healing, lesions with duration of more than 12 weeks were excluded. Ninety nine patients who met our criteria were in 2 groups. 52 patients were  $\leq 15$  y and 47 patients were  $> 15$  y. The patients were asked to come back clinic 20 days after beginning of the treatment and 45 days after the finishing for follow-up. They were strongly advised not to use any other therapeutic methods during this period. Intramuscular Meglimine Antimoniate (Glucantime®, Specia, Paris, France) was prescribed for each patient with the dosage of 60 mg/kg/day for 20 days. At each visit all patients were re-examined clinically for evaluating the response rate and it was determined by measuring the indurations as below: 1. Complete improvement (full re-epithelialization of the lesions and 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  $< 25\%$ . The study end points were complete healing of skin lesion or withdrawal from the study.

#### General information

##### Acronym

ETRSMACACLCAP

##### IRCT registration information

IRCT registration number: **IRCT138804162082N1**

Registration date: **2009-09-14, 1388/06/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-09-14, 1388/06/23

##### 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 Mashad University of Medical Sciences

##### Expected recruitment start date

2006-09-06, 1385/06/15

##### Expected recruitment end date

2007-09-06, 1386/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of therapeutic response to systemic Meglumine antimoniate (Glucantime) in children with acute Cutaneous Leishmaniasis comparing with adult patients

#### Public title

Comparing therapeutic response to systemic Meglumine Antimoniate (Glucantime) in children with acute Cutaneous Leishmaniasis versus adult patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: patients with acute cutaneous leishmaniasis (more than 4 months duration) Exclusion criteria: 1. History of allergy to Glucantim 2. History of Cardiac, Renal or hepatic diseases 3. Pregnancy or breast feeding 4. Performing other treatment for Cutaneous leishmaniasis during the study or in the last 3-month 5. If the patient was not available for follow-up of the treatment

#### Age

To **75 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **99**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

This is a clinical trial that evaluated and compared the response to systemic Glucantim with dosage of 60 mg/kg/day for 20 days in two groups of children and adult patients.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical committee of Mashad University of Medical Science

##### Street address

Central building of Mashad University of Medical Sciences

##### City

Mashhad

#### Postal code

9187973945

#### Approval date

2006-07-06, 1385/04/15

#### Ethics committee reference number

6109

## 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

at the end of 20th day of treatment and 45 days after finishing the treatment schedule

#### Method of measurement

Measurement of induration of the lesions ( ulcers)

## 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

Intramuscular (I.M.) glucantime with dosage of 60mg/kg/day for 20 days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinic of Cutaneous leishmaniasis, Qaem Hospital

##### Full name of responsible person

Dr Pouran Layegh

**Street address**

Department of Dermatology , Qaem Hospital

**City**

Mashhad

**2****Recruitment center****Name of recruitment center**

Clinic of Cutaneous leishmaniasis, Imam Reza Hospital

**Full name of responsible person**

Dr Ahmad REza Taheri

**Street address**

Department of Dermatology , Imam Reza Hospital

**City**

Mashad

**3****Recruitment center****Name of recruitment center**

Clinic of cutaneous Leishmaniasis, Villa Health center

**Full name of responsible person**

Dr Roya Shabahang, Dr Sara Rahsepar

**Street address**

Villa Health center, Villa Blv, Abobargh Blv

**City**

Mashad

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Research Council of Mashad University of Medical Sciences

**Full name of responsible person**

Research Council

**Street address**

Research Council office, 2nd floor, Central building of Mashad University of Medical Sciences, Daneshgah street

**City**

Mashad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Council of Mashad 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashad University of Medical Sciences

**Full name of responsible person**

Dr. Poursan Layegh

**Position**

Associate Professor

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

Department of Dermatology, Qaem Hospital, Ahmad Abad Avenue

**City**

Mashhad

**Postal code**

9176699199

**Phone**

+98 51 1881 4988

**Fax**

+98 51 1840 9612

**Email**

layeghpo@mums.ac.ir; pouran\_layegh@yahoo.com

**Web page address****Person responsible for updating data****Contact****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*