

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 ≤ 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

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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. Pouran Layegh

Position

Associate Professor

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

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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