

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 therapeutuc response to systemic Meglumine antimoniate (Glucantime) in children with acute Cutaneous Leishmaniasis comparing with adult patients		Postal code 9187973945
Public title Comparing therapeutuc response to systemic Meglumine Antimoniate (Glucantime) in children with acute Cutaneous Leishmaniasis versus adult patients		Approval date 2006-07-06, 1385/04/15
Purpose Treatment		Ethics committee reference number 6109
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		Health conditions studied 1 Description of health condition studied Cutaneous Leishmaniasis ICD-10 code B55.1 ICD-10 code description Cutaneous leishmaniasis
Age To 75 years old		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 Measurment of induration of the lesions (ulcers)
Gender Both		Secondary outcomes 1 Description Adverse Effects Timepoint Recorded at each follow-up visit Method of measurement Taking medical history and performing physical examination
Phase 3		Intervention groups 1 Description Intramuscular (I.M.) glucantime with dosage of 60mg/kg/day for 20 days Category Treatment - Drugs
Groups that have been masked <i>No information</i>		Recruitment centers 1 Recruitment center Name of recruitment center Clinic of Cutaneous leishmaniasis, Qaem Hospital Full name of responsible person Dr Pouran Layegh
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		

Street address

Department of Dermatology , Qaem Hospital

City

Mashhad

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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

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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