Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of theraputic 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

Country

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

Public title
Comparing theraputic 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
Measurment 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
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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