Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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 Mashad University of Medical Sciences
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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
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Person responsible for updating data

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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