

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

Name

Farahzad Jababri Azad

Name of organization / entity

Mashahd University of Medical Scineces

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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 Mashhad 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

Hadis Yousefzadeh

Position

Master of Sciences, Biologist

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Web page address

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