

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing improvement of lesions in leishmaniasis patients with two treatment methods including trichloroacetic Acid (TCA) and interalesional meglumine antimoniate (Glucantime) for the treatment of Lupoid leishmaniasis

Protocol summary

Summary

The aim of this study is to compare combined intra-lesional injection of Glucantime and topical application of aqueous solution of trichloroacetic Acid (TCA) 50% in the treatment of cutaneous leishmaniasis. A total of 120 patients who their cutaneous leishmaniasis will be diagnosed by direct skin smear via Giemsa method or dermal biopsy and their clinical lesion course is less than 6 months will be recruited to receive interalesional glucantime (until the lesions are completely indurated to 1 mm of their surrounding area) or topical solution of TCA until the lesion is frosted for 8 weeks. The changes of lesion indurations in every follow up visit will be measured as primary outcome measure. Patients will be followed up for 3 months after the final therapeutic course and lesion indurations and possible side effects will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101313862N6**

Registration date: **2011-04-11, 1390/01/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-04-11, 1390/01/22

Registrant information

Name

Farahzad Jababri Azad

Name of organization / entity

Mashahd University of Medical Scineces

Country

Iran (Islamic Republic of)

Phone

+98 51 1843 6626

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Recruitment status

Recruitment complete

Funding source

Funded by Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2009-11-26, 1388/09/05

Expected recruitment end date

2011-08-27, 1390/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing improvement of lesions in leishmaniasis patients with two treatment methods including trichloroacetic Acid (TCA) and interalesional meglumine antimoniate (Glucantime) for the treatment of Lupoid leishmaniasis

Public title

Comparing improvement of lesions in leishmaniasis patients with two treatment methods including trichloroacetic Acid (TCA) and interalesional meglumine antimoniate (Glucantime) for the treatment of Lupoid leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: presence of cutaneous leishmaniasis in less than 6 months prior to the study that their disease has been approved by direct smear and stained with Giemsa or positive dermal biopsy, 3-month treatment-free interval from the last treatment course
 Exclusion criteria: pregnancy, breast-feeding, any administration of any other medication during the study that has anti-leishmaniasis ingredient during 2 last months, history of severe renal impairment, pulmonary and cardiovascular disease

Age
 To 80 years old

Gender
 Both

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: 120

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 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

86721

Approval date

2009-09-27, 1388/07/05

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

first time at 8th weeks after treatment and the second time in follow up visit after 3 months of commencement of the study

Method of measurement

Measuring the width and induration and ulcer size

Secondary outcomes

1

Description

side effects

Timepoint

at each follow up visit

Method of measurement

Physical examination

Intervention groups

1

Description

Interalesional Glucantime injection, until the lesion with 1 mm of its surrounding is completely infiltrated, in size basis until the lesion is completely infiltrated and indurated, weekly up to 8 weeks

Category

Treatment - Drugs

2

Description

Topical TCA 50%, after the lesion is frosted, the lesion site without washing is covered with topical cream, weekly until improvement time and will repeat 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

Street address

Ghaem Hospital, Ahmad Abad Street

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

City

Mashhad

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

Hasan Amir Soleimani

Position

General Practitioner

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Dermatology, Ghaem Hospital, Mashad University of Medical Sciences

Full name of responsible person

Dr Mahnaz Banihashemi

Position

Associate Professor of Dermatology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Zamen Salamati Institute of healthcare services

Full name of responsible person

Hadis Yousefzadeh

Position

Master of Sciences, Biologist

Other areas of specialty/work

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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