Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Name of organization / entity
Mashahd University of Medical Scineces
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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 Mashad University of Medical Sciences
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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
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
Dr Mahnaz Banihashemi
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Associate Professor of Dermatology
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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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No. 86, Ibn Sina ave.,Zamen Salamati Institute
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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