Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A clinical study of the efficacy of oral allopurinol and itraconazole in comparison with parenteral meglumine antimoniate in the treatment of old-world cutaneous leishmaniasis in Mashhad

Protocol summary

Study aim
Determination of treatment effect of combination of oral allopurinol and itraconazole in comparison with parenteral MA in treatment of cutaneous leishmaniasis

Design
eligible people based on their personal choice enter one the the two groups of study and each group has 15 people and there is no need for randomization because our study is descriptive

Settings and conduct
diseases with leishmaniasis refer to dermatology clinic of Imam Reza Hospital, Mashhad

Participants/Inclusion and exclusion criteria
The disease should be diagnosed by direct smear Duration from time of diagnosis up to now is less than 6 months Not receiving any systemic treatment for leishmaniasis previously Not having immunosuppressive condition or contraindication for drugs

Intervention groups
IM Glucantim 20 mg/kg/day for 20 days in one group and Allopurinol 10 mg/kg/day and Itraconazole 4 mg/kg/day (both of them are oral) for the other group

Main outcome variables
size of lesion Result of treatment (cure, recurrency, failure) Tolerance of medication Side effects of treatment Compliance on treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250825066995N1**
Registration date: **2025-10-07, 1404/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-07, 1404/07/15**
Update count: **0**

Registration date
2025-10-07, 1404/07/15

Registrant information

Name
Sorour Attaran

Name of organization / entity

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Iran (Islamic Republic of)

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Email address
sorourattarang@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-09-30, 1404/07/08

Expected recruitment end date
2027-03-21, 1406/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical study of the efficacy of oral allopurinol and itraconazole in comparison with parenteral meglumine antimoniate in the treatment of old-world cutaneous leishmaniasis in Mashhad

Public title
Comparison of allopurinol and itraconazole with glucantim in treatment of leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The disease should be diagnosed by direct smear Duration from time of diagnosis up to now is less than 6 months Not receiving any systemic treatment for leishmaniasis previously Not having immunosuppressive condition or contraindication for drugs

Exclusion criteria:

Age

From **12 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

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

Dermatology clinic of Imam Reza Hospital, against Kafaei street, Daneshgah Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2025-07-09, 1404/04/18

Ethics committee reference number

4022671

Health conditions studied

1

Description of health condition studied

Cutaneous leishmaniasis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Size of lesion

Timepoint

45 and 90 days after treatment

Method of measurement

Ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Allopurinol 10 mg/kg/day and Itraconazole 4 mg/kg/day (both of them are oral)

Category

Treatment - Drugs

2

Description

Intervention group: IM Glucantim 20 mg/kg/day for 20 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic of Imam Reza hospital

Full name of responsible person

Sorour Attaran

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Sponsors / Funding sources

1

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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
Mashhad University of Medical Sciences
Proportion provided by this source
99
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
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Dermatology Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable

Title and more details about the data/document
all of data are sharable after making them anonymous
When the data will become available and for how long
6 months after publishing results
To whom data/document is available
data are available for scientific and academic researchers
Under which criteria data/document could be used
for data analysis
From where data/document is obtainable
send email to writer of article for receiving data
What processes are involved for a request to access data/document
after sending email to writer of article, during 1 month, data are sent to him/her
Comments