

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3879 9414

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 Kafaeei 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

Street address

Dermatology clinic of Imam Reza Hospital, against Kafaeei street, Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

sorourattarang@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad University of Medical science Goreyshi Building, Daneshgah Ave. Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

913753459

Phone

+98 51 3841 1538

Email

vcresearch@mums.ac.ir

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

Full name of responsible person

Sorour Attaran

Position

Dermatology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Dermatology clinic of Imam Reza Hospital, against Kafeai street, Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

sorourattarang@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Mashayekhi Goyonlo

Position

professor

Latest degree

Specialist

Other areas of specialty/work

dermatology

Street address

Imam Reza Hospital, Imam Reza Square, Ebne Sina Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2020

Email

mashayekhiv@mums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Mashayekhi Goyonlo

Position

professor

Latest degree

Specialist

Other areas of specialty/work

dermatology

Street address

Imam Reza Hospital, Imam Reza Square, Ebne Sina Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2020

Email

mashayekhiv@mums.ac.ir

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