

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of efficacy of intramuscular meglumine antimoniate plus oral allopurinol with intramuscular meglumine antimoniate alone in treatment of cutaneous leishmaniasis

Protocol summary

Study aim

Comparison of efficacy of intramuscular meglumine antimoniate plus oral allopurinol with intramuscular meglumine antimoniate alone in treatment of cutaneous leishmaniasis

Design

Clinical trial which is parallel group, double blind, randomized, phase 3 trial.

Settings and conduct

Dermatology Department Combined military hospital Quetta

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with biopsy proven leishmaniasis plus has lesion(s) located in sites not compatible with local treatment for example on or around eyes lesions in which scarring would be disfiguring like on face lesions that will have difficulting in healing like on lower limb or lesion ≥ 4 cm lesion with sporotrichoid spread Exclusion criteria: patients allergic to antimonials pregnant and breast feeding women patients having mucosal, mucocutaneous or visceral leishmaniasis Patients with comorbidity (diabetes, hypertension, chronic liver disease, chronic kidney disease) and/or immunosuppression Patients with baseline ECG abnormalities/

Intervention groups

Intervention group A: Patients were given drug via Intramuscular route injection meglumine antimoniate plus oral allopurinol. Intramuscular meglumine antimoniate was given in dose of 15mg/kg intramuscular if volume of injection exceeds 10ml as per body weight then it should be divided into two doses in each buttock and oral allopurinol was given 15mg/kg in the form of tablets Intervention group B: Patients were given drug via Intramuscular route meglumine antimoniate 15mg/kg if the volume of injection exceeds 10 ml, it should be divided into two doses: one in each buttock or thigh.

Main outcome variables

Clinical/treatment response

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210823052264N6**

Registration date: **2024-05-23, 1403/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2024-05-23, 1403/03/03**

Update count: **0**

Registration date

2024-05-23, 1403/03/03

Registrant information

Name

Najia Ahmed

Name of organization / entity

PNS shifa

Country

Pakistan

Phone

+92 81 2864092

Email address

najiaomer@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-10, 1403/02/21

Expected recruitment end date

2024-06-06, 1403/03/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of intramuscular meglumine antimoniate plus oral allopurinol with intramuscular meglumine antimoniate alone in treatment of cutaneous leishmaniasis

Public title

Comparison of efficacy of intramuscular meglumine antimoniate plus oral allopurinol with intramuscular meglumine antimoniate alone in treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with biopsy proven leishmaniasis or has lesion(s) located in sites not compatible with local treatment for example lesions on or around eyes Disfiguring lesion on face that lead to scarring Lesions difficult to heal like on lower limbs Lesion more than 4cm in size with sporotichoid spread Multiple lesions

Exclusion criteria:

patients allergic to antimonials Pregnant and breast feeding patients Patients having mucosal, mucocutaneous or visceral leishmaniasis Patients with comorbid (diabetes, hypertension, chronic liver disease, chronic kidney disease) Immunosuppression patients Baseline ECG abnormalities/heart disease

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomisation done by lottery method in which chits were kept in a jar and patient will be asked to pick one deciding their treatment regimen as per interventional group 1 and 2

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant and data analyser are blinded by lottery method only researcher knows about blinding method participant/patient picks up a chit from the jar and decides the treatment method as per interventional group 1 and 2

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Ethical Review Board Certificate-CMH
Quetta

Street address

Combined military hospital Quetta

City

Quetta

Postal code

08762

Approval date

2024-04-19, 1403/01/31

Ethics committee reference number

CMH QTA-IERB/2024

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**

Healing of lesion in response to treatment

Timepoint

before intervention and 2, 4, 6 and 8 weeks after intervention until complete healing occurs then patient called for followup after 4 weeks

Method of measurement

Clinical response

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group A: Patients were given drug via

Intramuscular route injection meglumine antimoniate 15mg/kg if dose exceeds 10ml then it should be divided into two doses given on each buttock plus oral allopurinol 15mg/kg in the form of tablets.

Category

Treatment - Drugs

2

Description

Intervention group B: Patients were given drug via Intramuscular route injection meglumine antimoniate 15mg/kg. If the volume of injection exceeds 10 ml, it should be divided into two doses: one in each buttock

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

CMH Quetta

Full name of responsible person

Dr Zainab Kazam

Street address

Combined military hospital Quetta

City

Quetta

Postal code

08762

Phone

+92 336 5534909

Email

zainokazam@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

CMH Quetta

Full name of responsible person

Dr Zainab Kazam

Street address

Combined military hospital Quetta

City

Quetta

Postal code

08762

Phone

+92 336 5534909

Email

zainokazam@gmail.com

Grant name

Combined military hospital Quetta

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

CMH Quetta

Proportion provided by this source

100

Public or private sector

Private

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

CMH Quetta

Full name of responsible person

Dr Zainab Kazam

Position

Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

CMH Quetta

City

Quetta

Province

Balochistan

Postal code

08762

Phone

+92 336 5534909

Email

zainokazam@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

CMH Quetta

Full name of responsible person

Dr Zainab Kazam

Position

Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

CMH Quetta

City

Quetta

Province

Balochistan

Postal code

08762

Phone

+92 336 5534909

Email

zainokazam@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

CMH Quetta

Full name of responsible person

Dr Zainab Kazam

Position

Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Combined military hospital Quetta

City

Quetta

Province

Balochistan

Postal code

08762

Phone

+92 336 5534909

Email

zainokazam@gmail.com

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Primary outcome

When the data will become available and for how long

One month after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Many

From where data/document is obtainable

zainokazam@gmail.com

What processes are involved for a request to access data/document

Request

Comments

NA