

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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  $\geq 4$  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 comorbids (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**

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**City**

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**Province**

Balochistan

**Postal code**

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**Phone**

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**Email**

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**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**

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**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**

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**Email**

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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**

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