Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 scaring 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 nd 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 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
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Postal code
08762
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+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
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Person responsible for scientific inquiries

Contact

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Latest degree
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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
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