

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Efficacy of Intravenous Versus Intramuscular Injection Meglumine Antimoniate in patients of Cutaneous Leishmaniasis

Protocol summary

Study aim

To Compare Efficacy of Intravenous versus Intramuscular Meglumine Antimoniate in Treatment of Cutaneous Leishmaniasis

Design

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

Settings and conduct

Dermatology Department, CMH Quetta

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA: Patients with biopsy proven cutaneous leishmaniasis and fulfilling the criteria for parenteral treatment with injection meglumine antimoniate. EXCLUSION CRITERIA: Patients of cutaneous leishmaniasis allergic to antimonial, having comorbidities (diabetes, hypertension, chronic liver disease, chronic kidney disease,), baseline ECG abnormality/heart disease, pregnant and breastfeeding women.

Intervention groups

Intervention group A: Patients were given drug via Intravenous route. The drug should be given diluted in 50-200 ml of 5% glucose solution over 30-60 minutes in ICU/HDU with cardiac monitoring. Intervention group B: Patients were given drug via Intramuscular route. 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 Response

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210823052264N4**

Registration date: **2024-04-03, 1403/01/15**

Registration timing: **registered_while_recruiting**

Last update: **2024-04-03, 1403/01/15**

Update count: **0**

Registration date

2024-04-03, 1403/01/15

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

2024-04-01, 1403/01/13

Expected recruitment end date

2024-10-01, 1403/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Efficacy of Intravenous Versus Intramuscular Injection Meglumine Antimoniate in patients of Cutaneous Leishmaniasis

Public title

Comparison of Efficacy of Intravenous Versus Intramuscular Injection Meglumine Antimoniate in patients of Cutaneous Leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with biopsy proven leishmaniasis plus any of the following: has lesion(s) located in sites not compatible with local treatment for example eyelids lesions in which scarring would be disabling or severely disfiguring like on face lesions that will have difficulting in healing like on lower limb or over a joint lesions involving mucosa or cartilage lesion ≥ 4 cm lesion with sporotrichoid spread multiple lesions

Exclusion criteria:
patients allergic to antimonials the lesion is already self-curing pregnant and breast feeding women those who refused to accept the diagnostic procedures 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/Heart disease

Age
From **15 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization done by lottery method, in which small chits of paper are kept in a jar and the patients will be asked to pick one deciding their treatment regimen.

Blinding (investigator's opinion)
Double blinded

Blinding description
participants and data analyzer were blinded

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
Ofh2 cmh quetta
City
Quetta
Postal code
08762
Approval date
2024-03-29, 1403/01/10
Ethics committee reference number
CMH QTA-IERB/18/2024

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 occur than patient called for followup after 4 weeks

Method of measurement

Clinical Response Evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: Patients were given drug via Intravenous route. The drug should be given diluted in 50-200 ml of 5% glucose solution over 30-60 minutes in ICU/HDU with cardiac monitoring

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

CMH Quetta

Full name of responsible person

Dr Shafia Shaikh

Street address

OFH2 C,H Quetta

City

Quetta

Postal code

08762

Phone

+92 324 4153402

Email

shafiashaikh994@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

CMH Quetta

Full name of responsible person

Dr. Shafia Shaikh

Street address

ofh2

City

quetta

Postal code

08734

Phone

+92 324 4153402

Email

shafiashaikh994@gmail.com

Grant name

CMH 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. Shafia Shaikh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

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City

quetta

Province

Balochistan

Postal code

08734

Phone

+92 324 4153402

Email

shafiashaikh994@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

CMH Quetta

Full name of responsible person

Dr. Shafia Shaikh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

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Phone

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Email

shafiashaikh994@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

CMH Quetta

Full name of responsible person

Dr. Shafia Shaikh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Phone

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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

shafishaikh994@gmail.com

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

Request

Comments

NA