Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 scaring 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 leishmaniaisis

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
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quetta
Postal code
08734
Phone
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Full name of responsible person
Dr. Shafia Shaikh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work

Dermatology

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Phone

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Email

shafiashaikh994@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

shafiashaikh994@gmail.com

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

Request

Comments

NA