

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

EFFICACY OF MILTEFOSINE AND ALLOPURINOL IN COMBINATION VERSUS MILTEFOSINE ALONE IN CUTANEOUS LEISHMANIASIS

Protocol summary

Study aim

TO STUDY EFFICACY OF MILTEFOSINE AND ALLOPURINOL IN COMBINATION VERSUS MILTEFOSINE ALONE IN 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 of both genders, aged 18-65 years with biopsy-proven cutaneous leishmaniasis. Plus • Positive LD bodies smear on Giemsa stain • Lesions in sites not responding to local treatment or meeting WHO guidelines • Multiple lesions on body • Lesions on lower legs, over a joint, mucosa or cartilage • Lesions located on sites not compatible with local treatment • Lesions that are potentially disfiguring or disabling (i.e. on face, fingers or toes) Exclusion criteria • People with comorbidity(diabetes, hypertension, chronic liver diseases, chronic kidney disease) and or immunocompromised • Allergy to Allopurinol,miltefosine and previous history of drug reactions to any drug. • Has lesions that are limited in size (papules, nodules or ulcerated nodules) • The lesion is already self-curing • Patients enrolled in other research protocols • Pregnant and breast feeding women • Those who refused to accept the diagnostic procedures • Children under 12 years of age

Intervention groups

Group A: Receives miltefosine (2.5 mg/kg) plus a placebo.(wt > 45 kg = 50 mg x TDS, < 45 kg 50mg x BID, max dose 150 mg /day) for 28 days. Group B: Receives miltefosine and allopurinol (20mg/kg)

Main outcome variables

Clinical Response

General information

Reason for update

Acronym

CL Cutaneous Leishmaniasis

IRCT registration information

IRCT registration number: **IRCT20210823052264N14**

Registration date: **2025-06-04, 1404/03/14**

Registration timing: **retrospective**

Last update: **2025-06-04, 1404/03/14**

Update count: **0**

Registration date

2025-06-04, 1404/03/14

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

2025-01-01, 1403/10/12

Expected recruitment end date

2025-06-30, 1404/04/09

Actual recruitment start date

2025-01-01, 1403/10/12

Actual recruitment end date

2025-05-31, 1404/03/10

Trial completion date

2025-07-01, 1404/04/10

Scientific title

EFFICACY OF MILTEFOSINE AND ALLOPURINOL IN COMBINATION VERSUS MILTEFOSINE ALONE IN CUTANEOUS LEISHMANIASIS

Public title

EFFICACY OF MILTEFOSINE AND ALLOPURINOL IN COMBINATION VERSUS MILTEFOSINE ALONE IN CUTANEOUS LEISHMANIASIS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients of both genders, aged 18-65 years with biopsy-proven cutaneous leishmaniasis. Plus • Positive LD bodies smear on Giemsa stain • Lesions in sites not responding to local treatment or meeting WHO guidelines • Multiple lesions on body • Lesions on lower legs, over a joint, mucosa or cartilage • Lesions located on sites not compatible with local treatment • Lesions that are potentially disfiguring or disabling (i.e. on face, fingers or toes)

Exclusion criteria:

• People with comorbidity (diabetes, hypertension, chronic liver diseases, chronic kidney disease) and or immunocompromised • Allergy to Allopurinol, miltefosine and previous history of drug reactions to any drug. • Has lesions that are limited in size (papules, nodules or ulcerated nodules) • The lesion is already self-curing • Patients enrolled in other research protocols • Pregnant and breast feeding women • Those who refused to accept the diagnostic procedures • Children under 12 years of age

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **74**

More than 1 sample in each individual

Number of samples in each individual: **0**
empty

Actual sample size reached: **74**

More than 1 sample in each individual

Actual sample size in each individual: **0**
empty

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

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

Block D15 flat E Sarwar COLONY Quetta cantonment

City

Quetta

Postal code

08762

Approval date

2025-01-01, 1403/10/12

Ethics committee reference number

CMH QTA - IERB /62/2024

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 follow-up after one month

Method of measurement

Clinical Response Evaluation

Secondary outcomes

1

Description

any side effects during leishmaniasis treatment

Timepoint

2, 4, 6, 8 weeks and 3 months after treatment

Method of measurement

interviewing with the patients and clinical examination

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

Intervention Group A: Receives miltefosine (2.5 mg/kg) plus a placebo.(wt > 45 kg = 50 mg x TDS, < 45 kg 50mg x BID, max dose 150 mg /day) for 28 days.

Category

Treatment - Drugs

2**Description**

Intervention group: Group B: Receives miltefosine and allopurinol (20mg/kg)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

CMH Quetta

Full name of responsible person

Dr Sammara Sarwar

Street address

Block D15 flat E Sarwar COLONY Quetta cantonment

City

Quetta

Postal code

08762

Phone

+92 340 0009994

Email

sammara.sarwar@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

CMH Quetta

Full name of responsible person

Dr Sammara Sarwar

Street address

Block D15 flat E Sarwar COLONY Quetta cantonment

City

Quetta

Postal code

08762

Phone

+92 340 0009994

Email

sammara.sarwar@gmail.com

Grant name

CMH Quetta

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

No

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 sammara sarwar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Block D15 flat E Sarwar COLONY Quetta cantonment

City

Quetta

Province

Balochistan

Postal code

08762

Phone

+92 340 0009994

Email

sammara.sarwar@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

CMH Quetta

Full name of responsible person

Dr Sammara Sarwar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Block D15 flat E Sarwar COLONY Quetta cantonment

City

Quetta
Province
Balochistan
Postal code
08762
Phone
+92 340 0009994
Email
sammara.sarwar@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
CMH Quetta
Full name of responsible person
Dr sammara sarwar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Block D15 flat E Sarwar COLONY Quetta cantonment
City
Quetta
Province
Balochistan
Postal code
08762
Phone
+92 340 0009994
Email

sammara.sarwar@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

sammara.sarwar@gmail.com

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

request

Comments

NA