Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 treament

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
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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
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Email
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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Latest degree
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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
sammara.sarwar@gmail.com

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

Comments
NA