

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of efficacy of infrared heat therapy with cryotherapy as an adjunct to meglumine antimoniate in treatment of cutaneous leishmaniasis

Protocol summary

Study aim

Comparison of efficacy of infrared heat therapy with cryotherapy as an adjunct to meglumine antimoniate in treatment of cutaneous leishmaniasis

Design

Clinical trial which is a parallel group, double blind, randomised, phase 3 trial

Settings and conduct

Dermatology department Combined military hospital Quetta

Participants/Inclusion and exclusion criteria

Inclusion criteria includes 18 years or older, diagnosis confirmed with biopsy and smear, caused by leishmania species amenable to treatment with meglumine antimoniate group 2 receiving cryotherapy twice a week with cryogun/cotton wisp applied on lesion unless appears white and meglumine antimoniate and group 3 receiving meglumine antimoniate alone

Exclusion criteria involves individuals with comorbidities, pregnant women, abnormal ECG, allergy to antimonials, compromised immune system, diffuse or visceral leishmaniasis,

Intervention groups

Patient, researcher and outcome assessor studying three groups, group 1, group 2 and group 3. Group 1 receiving infrared heat therapy twice a week 2 cycles of 10 mins session with gap of 2 minutes and meglumine antimoniate group 2 receiving cryotherapy twice a week with cryogun/cotton wisp applied on lesion unless appears white and meglumine antimoniate and group 3 receiving meglumine antimoniate alone

Main outcome variables

Clinical response

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210823052264N5**

Registration date: **2024-05-18, 1403/02/29**

Registration timing: **registered_while_recruiting**

Last update: **2024-05-18, 1403/02/29**

Update count: **0**

Registration date

2024-05-18, 1403/02/29

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

2024-05-16, 1403/02/27

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 infrared heat therapy with cryotherapy as an adjunct to meglumine antimoniate in treatment of cutaneous leishmaniasis

Public title

Comparison of efficacy of infrared heat therapy with cryotherapy as an adjunct to meglumine antimoniate in treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 years or older Lesion size 4cm or more Multiple lesion Lesion that will have difficulty in healing like on lower limb or over joint Biopsy proven cutaneous leishmaniasis

Exclusion criteria:

Patients with comorbidities(diabetes mellitus, hypertension, chronic kidney disease Abnormal ECG/heart disease Photosensitivity Pregnant women Individuals with compromised immune systems Diffuse cutaneous or visceral leishmaniasis

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomisation by lottery method in which treatment methods were written on chits and placed in jar and each patient would pick up a chit and would follow that treatment

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind technique is used where patient and data analyzer doesn't know only researcher knows about treatment methods

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/20/2024

Health conditions studied

1

Description of health condition studied

Cutaneous leishmaniasis is a skin disease caused by parasite leishmania major and leishmania tropica in Pakistan province balochistan

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Lesion complete healing with negative induration,ulceration,oozing,sporotrichoid distribution in response to treatment

Timepoint

Before intervention and 2,6,4,8 weeks after intervention until complete healing occur then patient called for follow up after 4 weeks

Method of measurement

Clinical response evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 receiving infrared heat therapy twice a week 2 cycles for 10 minutes with gap of 2 mins at a distance of 4cm and achieving temperature of 45 degree Celsius with meglumine antimoniate

Category

Treatment - Drugs

2

Description

Intervention group 2 receiving cryotherapy twice a week with cryogun/cotton wisp dipped in liquid nitrogen until lesion turns white and meglumine antimoniate

Category

Treatment - Drugs

3

Description

Intervention group 3 receiving only meglumine antimoniate injection 15mg/kg IM/IV

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Combined military hospital 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

Combined military hospital 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

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

Combined military hospital Quetta

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

Sponsor: country of origin

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Combined military hospital Quetta

Full name of responsible person

Dr Zainab Kazam

Position

Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Combined military hospital Quetta

City

Quetta

Province

Balochistan

Postal code

08762

Phone

+92 336 5534909

Email

zainokazam@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Combined military hospital Quetta

Full name of responsible person

Dr Zainab Kazam

Position

Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Combined military hospital Quetta

City

Quetta

Province

Balochistan

Postal code

08762

Phone

+92 336 5534909

Email

zainokazam@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Combined military hospital Quetta

Full name of responsible person

Dr Zainab kazam

Position

Registrar dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Combined military hospital quetta

City

Quetta

Province

Balochistan

Postal code

08762

Phone

+92 336 5534909

Email

zainokazam@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

Comparison of efficacy of infrared heat therapy with cryotherapy as an adjunct to meglumine antimoniate in treatment of cutaneous leishmaniasis 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