Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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 minutesand 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
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Dr Zainab Kazam
Position
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Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact
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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