Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Assessment of Sodium Stibogluconate/Meglumine Intralesional Therapy Versus Combination of Thermal Therapy with Sodium Stibogluconate/Meglumine intralesional Therapy for skin lesions in Cutaneous Leishmaniasis in Pakistan

Protocol summary

Study aim

1. To compare efficacy and safety of sodium stibogluconate/meglumine intralesional therapy in combination with local-thermal therapy and alone 3. To identify reduction in number of intralesional therapy sessions when combined with thermal therapy.

Design

open label, parallel group, randomized control trial

Settings and conduct

Public Sector Clinic in endemic area. Patients, fulfilling the criteria will be randomly assigned to treatment or control group after consent process. stratified randomization technique will be used

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 02 – 80 years of age, either gender, with diagnosis of cutaneous leishmaniasis (CL) by direct examination under microscopy, voluntarily agreeing to participate in the study and complying with study follow-up visits will be enrolled. Exclusion Criteria: • Other forms of Leishmaniasis • Patients already receiving treatment for CL • Known hypersensitivity to sodium stibogluconate/meglumine • Pregnancy/lactation • Comorbidities which affecting follow-up of study

Intervention groups

On first visit treatment group will have thermotherapy and control group will receive Meglumine. On subsequent weekly visits both groups will receive meglumine intralesional.

Main outcome variables

The primary outcome will be treatment response in randomly assigned participants assessed at 4th,8th & 12th week post-treatment. The appearance, induration and size of skin lesion will be measured (using regular scale/measuring tape) .Complete response means complete re-epithelialization with no signs of inflammation .Partial response means decrease in lesion size not more than 50%, without appearance of epidermal crease while failure to response meant no re-epithelialization or a positive direct smear at the end of treatment, at 8th or 12th week of treatment. Safety outcome will be observed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220529055013N2**
Registration date: **2024-02-02, 1402/11/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-02, 1402/11/13**
Update count: **0**

Registration date

2024-02-02, 1402/11/13

Registrant information

Name

Fauzia Gilani

Name of organization / entity

National University of Science & Technology

Country

Pakistan

Phone

+92 51 2300714

Email address

fauziagilani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-01, 1402/11/12

Expected recruitment end date

2025-02-01, 1403/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Assessment of Sodium Stibogluconate/Meglumine Intralesional Therapy Versus Combination of Thermal Therapy with Sodium Stibogluconate/Meglumine intralesional Therapy for skin lesions in Cutaneous Leishmaniasis in Pakistan

Public title

Comparative Assessment of Standard of Care Intralesional Therapy Versus Combination of Thermal Therapy with Standard of care intralesional Therapy for skin lesions in Cutaneous Leishmaniasis in Pakistan

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of cutaneous leishmaniasis by direct examination under microscopy voluntarily agreeing to participate in the study and complying with study follow-up visits will be considered for enrollment.

Exclusion criteria:

• Other forms of Leishmaniasis i.e., mucocutaneous and/or visceral leishmaniasis (clinical exclusion) Patients already receiving treatment for Cutaneous Leishmaniasis• Known hypersensitivity to stibogluconate/meglumine antimoniate Pregnancy/lactation Comorbidities or other illness which may hinder the completion and follow-up of study

Age

From **2 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **132**

More than 1 sample in each individual

Number of samples in each individual: **2**

Incase of failure of response (no re-epithelialization or a positive direct smear at the end of treatment), a second sample will be taken.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with Cutaneous Leishmaniasis presenting to clinical practice will be invited to participate in the study, after being diagnosed by microscopy. All the patients fulfilling the inclusion/exclusion criteria will be formally consented by data collector for participating in the study. Patients who will voluntarily agree to participate and comply with study protocol will be randomized to either treatment or control group by data collector. Stratified block randomization method will be used in this study, with patients stratified for number/size of skin lesion (mild to moderate/ severe disease) and age. Only those participants/guardian/parents of participants who will voluntarily consent to participate in the study will be enrolled. In following circumstances, the subjects may be withdrawn from the study prior the expected completion: • Failure of subject to adhere to the protocol requirements • Subject consent withdrawal Randomization sequences will be generated and secured in opaque envelopes and will be kept in lock & key in separate room which will be only opened at the time of consent taking and randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Bioethics Committee

Street address

Health Research Institute, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad

City

Islamabad

Postal code

44000

Approval date

2021-12-24, 1400/10/03

Ethics committee reference number

Ref: No.4-87/NBC-562/21/962

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
1. Assessment of treatment efficacy in terms of treatment response among both study groups, assessed after 4-6 therapy sessions

Timepoint
Week 0, week 4, Week 8, Week 12

Method of measurement
Treatment Response labelled as: Complete response (complete re-epithelialization, disappearance of edema, induration, and other signs of inflammation), Partial response (decrease in lesion size not more than 50%, without appearance of epidermal crease)• Failure to response (no re-epithelialization).

Secondary outcomes

1

Description
safety adverse effects

Timepoint
0week, 4 weeks, 8 weeks, 12 weeks

Method of measurement
Assessment of treatment safety in terms of occurrence of known/unknown device and drug reactions/side effects at each follow-up visit. Safety assessment is defined as:• Local side effects o Redness, Itching, Burning, Blister formation, Oozing.

Intervention groups

1

Description
Treatment group: In this group, the skin lesion of patient along with 2 cm border of healthy skin around the lesion will be disinfected with antiseptic, followed by administration of local anesthesia with lignocaine. The skin lesion will then be exposed to thermal therapy((ThermoMed Model 1.8, Chemosurgery Inc. Phoenix-USA), to heat the affected area of the skin. The target temperature of 50°C willl be maintained for 30 seconds until whole lesion is covered. The area between the electrodes covers 49–73 mm2, therefore, several thermotherapy applications will be given to cover the whole lesion. From second visit onwards, the patients belonging to intervention group will be administered intralesional Meglumine (1.5gm/5ml equivalent to 81mg of antimony per 01 ml) 1-5ml mixed with 1:1 1% lidocaine, depending on lesion size but not exceeding 5 ml of total in one session.

Category
Treatment - Devices

2

Description
Control group: Meglumine intralesional injection will be given as first treatment session, followed by weekly sessions. Treatment sessions will be repeated on a weekly basis in the same manner for both the groups, where 4-6 sessions will be provided depending on the treatment response. Treatment responses will be assessed in both groups weekly until the treatment ends (maximum of 5 sessions) and follow-up visits at 8th week and 12th week post-treatment will be completed. Acute adverse reactions, adverse events and post-treatment adverse events will also recorded for both the groups.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Public Sector Clinic in endemic area Shakardara

Full name of responsible person
Nafisa Tahir

Street address
Naseer Uddin Clinic Shakardara

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Shakardara KPK

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26380

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Email
dr.nafisa.tahir@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
TDR/EMRO /WHO

Full name of responsible person
Nafisa Tahir

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Jalan Teknokrat

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Cyberjaya

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Grant name
SGS-20-21

Grant code / Reference number
2021-1088476-0

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
TDR/EMRO /WHO

Proportion provided by this source
100

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

UN agencies and international organizations

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

National University of Medical Sciences

Full name of responsible person

Nafisa Tahir

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

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National University of Medical sciences

Full name of responsible person

Fauzia Fatima Gilani

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Research Associate

Latest degree

Master

Other areas of specialty/work

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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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Results from the study in the form of tables and graphs of primary and secondary will be shared

When the data will become available and for how long

The data will be kept for 2 years. The results and findings of the study will be available in the form of publication. The data details can be shared with the journal on demand.

To whom data/document is available

Principal Investigator and co-investigator

Under which criteria data/document could be used

The data document can be shared with the publishing journal on demand

From where data/document is obtainable

Can contact the principal investigator.

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

Principal investigator can be accessed through email. dr.nafisa.tahir@gmail.com

Comments