Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative efficacy of low dose oral dapsone and intralesional meglumine antimoniate with intralesional meglumine antimoniate in patients presenting with cutaneous leishmaniasis.

Protocol summary

Study aim

The objective of this study to compare the efficacy of dapsone and intralesional meglumine antimoniate with intralesional meglumine antimoniate in patients presenting with Cutaneous leishmaniasis.the study aims to show complete response; complete re-epithelialization, disappearance of edema, induration, lesions becoming flatter and turning from erythematous to residual hyperpigmentation in colour assessed on photograph and clinical examination.

Design

Community-based ,parallel , non blind , randomized controlled trial

Settings and conduct

This study will be conducted on patients presenting in Dermatology OPD fulfilling the inclusion criteria , Study is Not blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients between 16-60 years of age, patients with positive smear or skin biopsies for amastigotes, lesions four or less in number and no lesion more than 4cm in size. · Either gender · Willing to provide informed consent. Exclusion Criteria: Pregnant or lactating women, sporotrichoid spread, use of any anti-leishmania treatment in the past 3 months, lesions at sites that merit systemic antimonials, allergy to antimonials and patients with history of liver disease, patient having G6PD deficiency will be excluded from the study .

Intervention groups

Group-A will receive intralesional meglumine antimoniate weekly and Group-B will receive oral dapsone (initially 25 mg/day for 01 week then 50mg/day onwards) with monitoring of Blood CP and Liver function tests and weekly intralesional meglumine antimoniate.co

Main outcome variables

Showing complete response; complete re-epithelialization, disappearance of edema, induration, lesions becoming flatter and turning from erythematous to residual hyperpigmentation in colour assessed on photograph and clinical examination.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241028063523N3**
Registration date: **2024-11-25, 1403/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-25, 1403/09/05**
Update count: **0**

Registration date

2024-11-25, 1403/09/05

Registrant information

Name

Atiya Rahman

Name of organization / entity

Bahria University of Health Sciences Campus Karachi Pakistan

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Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-21, 1403/09/01

Expected recruitment end date

2025-05-21, 1404/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy of low dose oral dapsone and intralesional meglumine antimoniate with intralesional meglumine antimoniate in patients presenting with cutaneous leishmaniasis.

Public title

Comparative efficacy of low dose oral dapsone and intralesional meglumine antimoniate with intralesional meglumine antimoniate in patients presenting with cutaneous leishmaniasis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

·Patients between 16-60 years of age, patients with positive smear or skin biopsies for amastigotes, lesions four or less in number and no lesion more than 4cm in size.· Either gender· Willing to provide informed consent.

Exclusion criteria:

Pregnant or lactating women, sporotrichoid spread, use of any anti-leishmania treatment in the past 3 months, lesions at sites that merit systemic antimonials, allergy to antimonials and patients with history of liver disease,patient having G6PD deficiency will be excluded from the study

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients presenting in the OPD of the Dermatology Department of PNS Shifa fulfilling the inclusion criteria will be included in this study. Written informed consent from the participants will be taken. Patients will be divided into two groups using lottery method. Demographic details which include age, weight, BMI, duration of disease, size , site and no. of lesions and gender will be noted and will be recorded on the approved performa. Group-A will receive intralesional meglumine antimoniate weekly and Group-B will receive oral dapsone (initially 25 mg/day for 01 week then 50mg/day onwards) with monitoring of Blood CP and Liver function tests and weekly intralesional meglumine antimoniate. Participants will be treated for 16 weeks or earlier if has occurred, whatever will be happened earlier. They will be evaluated in the 4th, 8th, 12th, 16th weeks of the treatment for efficacy.

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

Ethical committee PNS SHIFA

Street address

PNS Shifa Hospital, Sailor street DHA phase ll , near Kala pul

City

Karachi

Postal code

07557

Approval date

2024-11-18, 1403/08/28

Ethics committee reference number

ERC/2024/Derma/124

Health conditions studied

1

Description of health condition studied

Cutaneous leishmaniasis is caused by an “intracellular parasite” that is transferred to humans by a sand fly bite. It is endemic throughout Asia, Africa, Mediterranean region and America. It is estimated that there are between 0.7 to 1.2 million new cases of CL per year worldwide. It is a neglected third commonest vector borne disease in the world. It is widely spread in different parts of the world including South and Central America, Mediterranean Basin, Middle East and Central Asia.Leishmania tropicalis has a common association with the late ulcerative or dry urban type. The L. major causes the “wet, rural, or early” ulcerative type, which is characterized by many, eg’ often healing ulcers within a year. Mucocutaneous leishmaniasis, leishmaniasis recidivans, and diffuse cutaneous leishmaniasis are the rarest types of the disease .

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description
Efficacy will be labeled if patients with CL lesion in either group showed complete response; complete re-epithelialization, disappearance of edema, induration, lesions becoming flatter and turning from erythematous to residual hyperpigmentation in colour assessed on photograph and clinical examination.

Timepoint
Patient will be assessed before intervention and 4th ,8th , 12th , 16th weeks after intervention

Method of measurement
Patients having a typical, non-healing, painless, indurated papule, nodule, or plaque with or without crust on clinical assessment will labeled as having cutaneous leishmaniasis and will be confirmed by a direct smear taken from the lesions, which will then be stained with Giemsa stain showing Leishman bodies (amastigotes) on microscopic examination. , Skin biopsy to be done if required to confirm diagnosis.

Secondary outcomes

1

Description
Side effects: Monitoring and documenting adverse effects related to the treatment, such as hemolysis, methemoglobinemia, peripheral neuropathy, allergic dermatitis, headache,

Timepoint
4th, 8th, 12th, 16th weeks

Method of measurement
Patients having a typical, non-healing, painless, indurated papule, nodule, or plaque with or without crust on clinical assessment will labeled as having cutaneous leishmaniasis and will be confirmed by a direct smear taken from the lesions, which will then be stained with Giemsa stain showing Leishman bodies (amastigotes) on microscopic examination. , Skin biopsy to be done if required to confirm diagnosis.

Intervention groups

1

Description
Intervention group: Confirmed cases of cutaneous leishmaniasis will be divided into 02 groups .Group-A and Group-B. Group-A will receive intralesional meglumine antimoniate weekly and Group-B will receive oral dapsone (initially 25 mg/day for 01 week then 50mg/day onwards) with monitoring of Blood CP and Liver function tests and weekly intralesional meglumine antimoniate.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
PNS SHIFA HOSPITAL

Full name of responsible person
Jotee Rani

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Pns Shifa Hospital, sailors street DHA Phase 2 , main korangi road near kalapul Karachi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Armed forces Hospital PNS Shifa Hospital Karachi, Pakistan

Full name of responsible person
Dr Jotee Rani

Street address
Sailor street , DHA phase II , PNS SHIFA HOSPITAL near Kala pul

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Grant name

Grant code / Reference number

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

Title of funding source
Armed forces Hospital PNS Shifa Hospital Karachi, Pakistan

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Armed forces Hospital , PNS SHIFA

Full name of responsible person
Dr ATIYA RAHMAN

Position
Consultant

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Sailor street, DHA PHASE II, PNS SHIFA HOSPITAL NEAR KALA PUL

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Full name of responsible person
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
APPENDIX 1: PROFORMA COMPARATIVE EFFICACY OF LOW DOSE ORAL DAPSONE AND INTRALESIONAL MEGLUMINE ANTIMONIATE WITH INTRALESIONAL MEGLUMINE ANTIMONIATE IN PATIENTS PRESENTING WITH CUTANEOUS LEISHMANIASIS– A RANDOMIZED CONTROLLED TRIAL Name: _____ Age (years): _____ Weight (kg): _____ BMI (kg/m2): _____ Duration (weeks) : _____ Gender: Male/Female Size of lesion: Site of lesion: No. of lesion: Site: · Trunk · Arm · Hand · Leg · Feet Group: A (I/L meglumine antimoniate weekly) Group : B (Oral dapsone 50 mg/day and weekly I/L meglumine antimoniate) OUTCOME VARIABLE: EFFICACY: YES/NO

When the data will become available and for how long
After 6 months RCT , for 4 years

To whom data/document is available
Primary investigator

Under which criteria data/document could be used
All patients in Dermatology OPD according to operational definition of cutaneous leishmaniasis fulling the inclusion criteria

From where data/document is obtainable

Administration of PNS SHIFA HOSPITAL

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

Contact to primary investigator

Comments