Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation of the therapeutic effect of topical LeishG1 cream combined with intralesional injection of meglumine antimoniate (Glucantime) compared to the control group (intralesional injection of Glucantime and topical placebo cream) for the treatment of patients with cutaneous leishmaniasis caused by Leishmania tropica in humans based on a randomized, double-blind clinical trial

Protocol summary

Study aim

Evaluation of the therapeutic effect of intralesional Glucantime® injection combined with topical LeishG1 cream compared to intralesional Glucantime® injection with topical placebo cream on the cutaneous lesions of patients with CL caused by L.tropica

Design

Randomized, controlled clinical trial with parallel groups, double-blind, Phase 3 on 140 samples. Randomization is performed using the RAND function in Microsoft Excel.

Settings and conduct

This clinical trial will be conducted in Mashhad on eligible patients with active CL caused by L.tropica. Patients will be randomly assigned to two groups using randomised blocks, and the creams will be supplied in the same packaging with an identifiable code only. The subjects, the clinical caregiver and the outcome assessor will be blinded to the type of intervention. The treatment process includes intralesional injection of Glucantim and topical cream application for three months, and the epithelialisation process and side effects will be assessed at specific times.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: active cutaneous leishmaniasis lesion caused by Leishmania tropica, age 12-60 years, a maximum of 5 lesions per participant, the largest diameter of lesions less than 5 cm. Exclusion Criteria: atypical lesions or lesions located in sensitive areas of the body, lopoid or treatment-resistant forms of CL, pregnant or lactating women.

Intervention groups

Group 1: Treatment with Glucantime® by intralesional injection once a week for a maximum duration of 12 weeks, combined with topical application of LeishG1 cream twice daily on the lesion for 3 months. Group 2: Treatment with Glucantime® by intralesional injection once a week for a maximum duration of 12 weeks, combined with topical application of placebo cream twice daily on the lesion for 3 months.

Main outcome variables

Re-epithelialization of the lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240304061158N5**
Registration date: **2025-10-27, 1404/08/05**
Registration timing: **prospective**

Last update: **2025-10-27, 1404/08/05**
Update count: **0**

Registration date

2025-10-27, 1404/08/05

Registrant information

Name

fariba nemati

Name of organization / entity

Behpad Teb Iranian

Country

Iran (Islamic Republic of)

Phone

+98 21 6642 6890

Email address

info@behpadti.com

Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-01-21, 1404/11/01
Expected recruitment end date
2028-07-22, 1407/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the therapeutic effect of topical LeishG1 cream combined with intralesional injection of meglumine antimoniate (Glucantime) compared to the control group (intralesional injection of Glucantime and topical placebo cream) for the treatment of patients with cutaneous leishmaniasis caused by Leishmania tropica in humans based on a randomized, double-blind clinical trial

Public title
Evaluation of the therapeutic effect of LeishG1 topical cream for the treatment of patients with cutaneous leishmaniasis caused by Leishmania tropica
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of an active cutaneous leishmaniasis lesion caused by Leishmania tropica, confirmed by parasitological examinations including direct smear and PCR Age between 12 and 60 years Awareness of the study procedures Willingness to participate in the study and signing of the informed consent form A maximum of 5 lesions per participant The largest diameter of cutaneous lesions less than or equal to 5 cm
Exclusion criteria:
Suspected individuals to the disease Absence of Leishmania bodies in cutaneous lesions Number of lesions more than 5 Atypical lesions or lesions located in sensitive areas of the body (e.g., lips, ears, joints) Mean ulcer size greater than 5 cm Lipoid or treatment-resistant forms of cutaneous leishmaniasis Pregnant and lactating women Concurrent use of other anti-leishmanial medications Presence of dermatologic diseases such as eczema, psoriasis, lupus, pemphigus, fungal infections, and similar conditions Participation in the same research project
Age
From **12 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **140**
More than 1 sample in each individual
Number of samples in each individual: **5**
The number of skin lesions is up to 5 per participant.
Randomization (investigator's opinion)
Randomized
Randomization description
After identifying eligible patients, random allocation into two groups will be performed using a block randomization method. Four blocks will be generated with combinations of codes AABB, ABAB, ABBA, BAAB, BABA, and BBAA corresponding to the drug and placebo groups. The blocks will then be randomly selected using the RAND function in Microsoft Excel until the desired sample size is achieved. Group assignment will be carried out using 154 opaque sealed envelopes labeled externally with the group number and containing information about the intervention type inside each envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both the drug and placebo are packaged identically and can only be distinguished by a code for identification. This blinding procedure is applied to patients, investigators, clinical monitors, outcome assessors, and data analysts. At the end of the study, following final data analysis, the codes will be unblinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Public Health & Allied Medical Sciences- Tehran University o
Street address
Ethics Committee in Biomedical Research, Tehran university of medical sciences - Keshavarz Boulevard - Intersection of Qods Street - Central Building of Tehran University of Medical Sciences - 6th Floor - Room 604
City
Tehran
Province
Tehran
Postal code

1417614411

Approval date

2025-10-06, 1404/07/14

Ethics committee reference number

IR.TUMS.SPH.REC.1404.169

Health conditions studied

1

Description of health condition studied

Cutaneous leishmaniasis caused by Leishmania tropica

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Complete re-epithelialization: an skin lesion that is completely re-epithelialised by the end of the 12-week treatment period (i.e., 3 months).

Timepoint

Two weeks and one, two, and three months after the initiation of treatment

Method of measurement

The percentage of re-epithelialization of the lesion(s) will be calculated by comparing the ulcer size at baseline to the ulcer size at follow-up visits. Measurements will be taken in two perpendicular directions using a caliper or ruler. The ulcer area will be calculated using the elliptical area formula.

Secondary outcomes

1

Description

Adverse events

Timepoint

Days 0, 14, 28, two months, and three months after the initiation of treatment

Method of measurement

Follow-up and examination

2

Description

Relapse

Timepoint

Three to six months after the end of treatment

Method of measurement

An skin lesion that reaches 100% re-epithelialization by day 90 and subsequently relapse by day 180.

Intervention groups

1

Description

Intervention group: 70 patients with skin lesions caused by Leishmania tropica, treated with meglumine antimonate according to the national protocol in the form of intralesional injection once a week for a maximum of 12 weeks, along with treatment with LeishG1 cream (produced by Behpad Teb Iranian Company) twice a day for 3 months, applied as a thin layer on the lesion, the size of a knuckle.

Category

Treatment - Drugs

2

Description

Control group: 70 patients with skin lesions caused by Leishmania tropica, treated with meglumine antimonate according to the national protocol in the form of intralesional injection once a week for a maximum of 12 weeks, along with treatment with placebo cream (produced by Behpad Teb Iranian Company) twice a day for 3 months, applied as a thin layer on the lesion, the size of a knuckle.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center of Martyrs of Health-Mashhad

Full name of responsible person

Dr. Vahid Mashayekhi

Street address

Mashhad, Moalem Blvd., Moalem 75, Moalem 75.6

City

Mashhad

Province

Razavi Khorasan

Postal code

mashayekhiv@mums.ac.

Phone

+98 51 3509 2770

Email

mashayekhiv@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Tooba Ghazanfari

Street address

No 1471, Immunoregulation Research Center, Research Centers of Shahed University, North Kargar

Ave, Tehran, Iran.

City
Tehran

Province
Tehran

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1417953836

Phone
+98 21 6641 9712

Email
irrc@shahed.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahed University

Proportion provided by this source
60

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
Academic

2

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mehdi Mohebali

Street address
Tehran, Poursina Street, Tehran University of Medical Sciences, school of Public Health

City
Tehran

Province
Tehran

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1471616381

Phone
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Email
mohebali@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
40

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahed University

Full name of responsible person
Azadeh Rashidi

Position
Master of science

Latest degree
Master

Other areas of specialty/work
Immunology

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No 1471, Immunoregulation Research Center, Research Centers of Shahed University, North Kargar Ave, Tehran, Iran.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mehdi Mohebali

Position
Professor (The first of principle investigator)

Latest degree
Ph.D.

Other areas of specialty/work
Parasitology

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Tehran, Poursina Street, Tehran University of Medical Sciences, School of Public Health

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Person responsible for updating data

Contact

Name of organization / entity
Shahed University

Full name of responsible person
Azadeh Rashidi

Position
master of science

Latest degree
Master

Other areas of specialty/work
Immunology

Street address
No 1471, Immunoregulation Research Center, Research Centers of Shahed University, North Kargar Ave, Tehran, Iran.

City
Tehran

Province
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Ethical consideration about patient information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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