

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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, lipooid 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@behpadi.com

**Recruitment status**

recruiting

**Funding source**

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

**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

**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.

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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 Mohebbali

**Street address**

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

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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**

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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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mehdi Mohebbali

**Position**

Professor (The first of principle investigator)

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Parasitology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahed University

**Full name of responsible person**

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**Position**

master of science

**Latest degree**

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**Other areas of specialty/work**

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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