

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### Evaluating the effectiveness of intralesional injection of Glucantime® plus cotton boll extract compared to intralesional injection of Glucantime® plus cryotherapy in patients infected with Leishmania tropica

#### Protocol summary

##### Study aim

Evaluating the effect of Cotton boll extract compared to cryotherapy in healing of Cutaneous lesions by Leishmania tropica

##### Design

Phase 3; Pilot Open label randomized control trial with 24 samples that randomized by online block randomization generator

##### Settings and conduct

Study will be conducted in Kerman city leishmanial treatment center and patient with skin lesions by Leishmania tropica enroll by inclusion criteria and divide randomly into intervention and control groups. intervention group receive standard intralesional injection of Glucantime® plus 10% topical cotton boll extract for 8 weeks. Control group receive standard intralesional injection of Glucantime® plus cryotherapy for 8 weeks

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Infection by Leishmania tropica, Age within 8 to 60 years, Number of skin lesions less than 5, Size of lesions less than 5 centimeters, Duration of lesions less than 3 months, Receiving no anti-leishmanial remedies during past 3 months, Completing of informed consent form Exclusion criteria: Pregnancy and Lactation; Underlying diseases and Allergy; Lesions on joint or face and sensitive organs; Regional adenopathy

##### Intervention groups

Patients in intervention group receive 10% Topical cotton boll extract Patients in control group receive lesion Cryotherapy Intervention and control groups receive Intralesional injection of Glucantime®

##### Main outcome variables

Size of wound; Induration of wound; Healing time

#### General information

##### Reason for update

Sample size change

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230903059337N2**

Registration date: **2023-10-24, 1402/08/02**

Registration timing: **prospective**

Last update: **2025-10-07, 1404/07/15**

Update count: **1**

##### Registration date

2023-10-24, 1402/08/02

##### Registrant information

###### Name

Mehdi Shafiei\_bafti

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3131 5724

###### Email address

kmushafiei51@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-22, 1402/10/01

##### Expected recruitment end date

2025-08-21, 1404/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the effectiveness of intralesional injection of Glucantime® plus cotton boll extract compared to intralesional injection of Glucantime® plus cryotherapy in patients infected with Leishmania tropica

**Public title**

Effect of Cotton boll extract in treatment of Cutaneous leishmaniasis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients infected by Leishmania tropica Number of skin lesions less than 5 Size of lesions less than 5 centimeters Duration of lesions less than 3 months Receiving no anti-leishmania remedies during the past 3 months Completing the informed consent form

**Exclusion criteria:**

Pregnancy and Lactation Underlying diseases and Allergy Lesions on joint, face and sensitive organs Regional adenopathy

**Age**

From **8 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided into intervention and control group with Blocked randomization method by online block randomization generator

**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**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2023-10-23, 1402/08/01

**Ethics committee reference number**

IR.IUMS.REC.1402.643

**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**

Size of induration

**Timepoint**

In 0, 4, 8, 12 weeks of treatment

**Method of measurement**

By digital caliper

**2****Description**

Size of wound

**Timepoint**

In 0, 4, 8, 12 weeks of treatment

**Method of measurement**

Wound Desk app and digital caliper

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Intralesional injection of Glucantime® weekly for 8 weeks plus topical use of 10% Cotton boll extract twice a day for 8 weeks

**Category**

Treatment - Drugs

## 2

### Description

Control group: Intralesional injection of Glucantime® weekly for 8 weeks plus Cryotherapy once every two weeks for 8 weeks

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Leishmania treatment center

##### Full name of responsible person

Mehdi Shafiei\_bafti

##### Street address

Leishmania treatment center, Behzad st.

##### City

Kerman

##### Province

Kerman

##### Postal code

7618747654

##### Phone

+98 34 3323 0990

##### Email

kmushafiei51@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Reza Falak

##### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 8670 2504

##### Email

falak.r@iums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Iran University of Medical Sciences

##### 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

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Mehdi Shafiei\_bafti

#### Position

PhD student

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Traditional Medicine

#### Street address

School of Persian Medicine, No. 847, Behesht Ave., Abusaid St.

#### City

Tehran

#### Province

Tehran

#### Postal code

1114733311

#### Phone

+98 21 5558 0388

#### Email

kmushafiei51@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Maryam Taghavi Shirazi

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Traditional Medicine

#### Street address

School of Persian Medicine, No. 847, Behesht Ave., Abusaid St.

#### City

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#### Province

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#### Postal code

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#### Phone

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**Email**

mtaghavish@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mehdi Shafiei\_bafti

**Position**

Ph.D Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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**

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

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Research data can be shared as an Excel file without personal information

**When the data will become available and for how long**

6 months after Publication

**To whom data/document is available**

Academic Researchers

**Under which criteria data/document could be used**

For statistical analysis and papers with declaring the data source

**From where data/document is obtainable**

School of Persian medicine, Iran University of Medical Sciences

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

Sending an official request to announced address

**Comments**