Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Position
PhD student
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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