Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the Additive Effect of Tamoxifen ointment 0.5% Intralesional Glucantim injection in Patients with Cutaneous Leishmaniasis: A Randomized triple-Blind Clinical Trial

Protocol summary

Study aim
Assessment of the Adjunctive Effect of Topical Tamoxifen Ointment on the Efficacy of Standard Glucantime Therapy in Patients with Cutaneous Leishmaniasis

Design
randomized, triple-blind, parallel-group, controlled clinical trial involving 60 patients

Settings and conduct
A total of 60 patients with a confirmed diagnosis of cutaneous leishmaniasis, will be recruited from the dermatology clinics of Imam Reza Hospital, Hasheminejad Hospital, and affiliated health centers in Mashhad. After providing written informed consent, eligible participants will be enrolled in the study and randomly assigned to either the intervention group or the placebo group, with 30 patients allocated to each group. Random allocation will be performed using a block randomization method with a 1:1 allocation ratio.

Participants/Inclusion and exclusion criteria
Inclusion * Diagnosis of cutaneous leishmaniasis. * 18_60 years. * Absence of underlying conditions that contraindicate tamoxifen therapy (e.g., hypertension or unexplained vaginal bleeding). * Absence of significant systemic diseases, including uncontrolled diabetes mellitus and immunodeficiency disorders. Exclusion * Pregnancy or breastfeeding *allergy to ointment.

Intervention groups
patients will be randomly assigned to either the intervention group or the placebo group. All participants will receive standard treatment with Glucantime according to the treatment protocol. participants will receive either topical tamoxifen ointment or placebo ointment throughout the treatment period.

Main outcome variables
Lesions in both groups will be assessed for size, induration, clinical improvement, local adverse effects, and recurrence at baseline, weeks 4, 8, and 12, and 3–6 months after treatment completion.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260620069888N1**
Registration date: **2026-06-22, 1405/04/01**
Registration timing: **prospective**

Last update: **2026-06-22, 1405/04/01**
Update count: **0**

Registration date
2026-06-22, 1405/04/01

Registrant information

Name
Mohadeseh Tiravar

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-01, 1405/04/10

Expected recruitment end date
2026-11-21, 1405/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Additive Effect of Tamoxifen ointment 0.5% Intralesional Glucantim injection in Patients with Cutaneous Leishmaniasis: A Randomized triple-Blind Clinical Trial

Public title
Evaluation of the Added Effect of 0.5% Topical Tamoxifen Ointment Concurrently with Intralesional Glucantime Therapy in Patients with Cutaneous Leishmaniasis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
* Confirmed diagnosis of cutaneous leishmaniasis (by smear microscopy or PCR)* Age between 18 and 60 years* A maximum of 3 active lesions, each with a diameter of <4 cm* Written informed consent* Duration of lesions less than 6 months* No underlying conditions that contraindicate tamoxifen therapy (e.g., hypertension, unexplained vaginal bleeding)* No significant systemic diseases (e.g., uncontrolled diabetes mellitus, immunodeficiency)* No prior use of anti-leishmanial medications before enrollment

Exclusion criteria:

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization was employed in this study. Eligible cutaneous lesions were randomly assigned in equal numbers to two groups using blocks of four. To achieve this, 15 blocks of four were initially generated, with the random sequence within each block created using Microsoft Excel. The blocks were then randomly ordered without replacement, and participants were allocated to either Group A or Group B according to the predetermined sequence. This process continued consecutively until the required sample size was reached. Allocation concealment was ensured through the use of sealed, opaque envelopes containing the randomization sequence generated during the random allocation process. Based on the study sample size, a corresponding number of opaque envelopes were prepared. Each random allocation sequence was recorded on a card and placed inside an envelope. To preserve the randomization order, the envelopes were sequentially numbered on the outside according to the allocation sequence. Finally, all envelopes were sealed and remained unopened until participant assignment.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Following enrollment, participants will be randomly allocated to one of two study groups using a block randomization table: 1. Intralesional Glucantime (meglumine antimoniate) + placebo ointment (ointment base) 2. Intralesional Glucantime (meglumine antimoniate) + 0.5% tamoxifen ointment in a petrolatum base Both ointments will be prepared in the laboratory of the Faculty of Pharmacology, Mashhad University of Medical Sciences. The formulations will be packaged with identical appearance and labeling codes to ensure concealment of treatment allocation. The study will be conducted as a triple-blind trial. Participants, the evaluating physician, and the data analyst will remain unaware of treatment assignments throughout the study period.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Ghaem mehmansara, Ghaem hospital, Ahmadabad Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9176699311

Approval date
2026-05-10, 1405/02/20

Ethics committee reference number
IR.MUMS.IRH.REC.1405.024

Health conditions studied

1

Description of health condition studied
Cutaneous leishmaniosis

ICD-10 code
B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description
Lesion size and induration of cutaneous leishmaniasis lesions, clinical improvement, adverse effects, and recurrence
Timepoint
At baseline, weeks 4, 8, and 12, and 3–6 months after treatment completion
Method of measurement
Digital caliper

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Treatment with topical tamoxifen ointment applied to the lesions twice daily, in combination with weekly intralesional Glucantime injections.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam_Reza hospital
Full name of responsible person
Mohadese Tiravar
Street address
Mehmansara Ghaem, Ghaem Hospital, Ahmadabad Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Vice-Chancellor for Research and Technology, Mashhad University of Medical Sciences
Street address
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mohadeseh Tiravar
Position
Dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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