

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of two therapeutical methods including intralesional injection of glucantime alone and with low-level laser therapy in the treatment of acute cutaneous leishmaniasis

Protocol summary

Study aim

Determination and comparison of the improvement of acute cutaneous leishmaniasis lesions in patients undergoing intralesional injection of glucantime with and without low-level laser therapy

Design

A randomized single-blind clinical trial, with the parallel groups

Settings and conduct

In this study, 54 patients with acute cutaneous leishmaniasis will be included in the study and randomly divided into two groups. Patients in the first group will be treated only with intralesional glucantime injection and patients in the second group will be treated with low-level laser in addition to glucantime injection. The extent of lesion healing will then be assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria are proven diagnosis of acute rural cutaneous leishmaniasis by testing, the number of lesions of less than 4, the disease course of fewer than 100 days, lesions size of less than 3 cm, no lesion on the eyelid (within a distance of less than 2 cm from the eyelid), aged more than 5 years old and no lesion on the cartilage or joint and face. Exclusion criteria also are the presence of sporotrichoid or satellite lesions, taking immunosuppressive drugs during the last 6 months, a history of receiving topical or systemic anti-leishmaniasis treatment in the last month.

Intervention groups

Control group: Patients in the first group are treated only with intralesional injection of glucantime. The patient receives a topical injection of glucantime 0.5 to 1.5 cc per week per lesion; So that all around the lesion becomes white. Intervention group: Patients in the second group are also treated with an intralesional injection of glucantime (similar to the control group). In addition, patients were treated by a low-level laser using

an 820 nm probe, 3 times a week for a total of 10 sessions. Topical treatment with injectable glucantime lasts up to 8 weeks.

Main outcome variables

Lesion healing; Lesion area; Recurrence of the lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N14**

Registration date: **2020-12-07, 1399/09/17**

Registration timing: **prospective**

Last update: **2020-12-07, 1399/09/17**

Update count: **0**

Registration date

2020-12-07, 1399/09/17

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of two therapeutical methods including intralesional injection of glucantime alone and with low-level laser therapy in the treatment of acute cutaneous leishmaniasis

Public title

The effect of intralesional injection of glucantime with low-level laser therapy in the treatment of acute cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Proven diagnosis of acute rural cutaneous leishmaniasis by testing The number of lesions of less than 4 The disease course of fewer than 100 days Lesion size of less than 3 cm No lesion on the eyelid (less than 2 cm from the eyelid) Aged over 5 years old No lesion on cartilage or joint and face

Exclusion criteria:

Presence of sporotrichoid lesions or satellite lesions Taking immunosuppressive drugs during the last 6 months The history of receiving topical or systemic anti-leishmaniasis treatment in the past month Lack of consent to participate in the study

AgeFrom **5 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **54****Randomization (investigator's opinion)**

Randomized

Randomization description

54 eligible patients will be simply randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. In this way, each of the generated codes will be assigned to a patient by chance, and therefore that patient will be studied in one of the two groups according to the code.

Blinding (investigator's opinion)

Single blinded

Blinding description

Given that in this study both groups will be undergone glucantime injection and only one of these two groups will be treated with low-level laser therapy, so the

patient and the care provider are aware of the type of intervention, but the researcher, results' evaluator, and data analyst will not have information of the two groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

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Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

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Isfahan

Postal code

8179964167

Approval date

2020-11-01, 1399/08/11

Ethics committee reference number

IR.MUI.MED.REC.1399.630

Health conditions studied**1****Description of health condition studied**

Acute cutaneous leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes**1****Description**

Lesion healing

Timepoint

The first to twelfth weeks from the beginning of the intervention

Method of measurement

Observation

2**Description**

Lesion area

Timepoint

The first to twelfth weeks from the beginning of the intervention

Method of measurement

Ruler

Secondary outcomes**1****Description**

Recurrence of the lesion

Timepoint

Three months and six months after the intervention

Method of measurement

Observation

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

Control group: Patients in the first group are treated only with intralesional injection of glucantime(Sanofi Company). The patient receives a topical injection of glucantime 0.5 to 1.5 cc per week per lesion; So that all around the lesion (one millimeter ring around it) becomes white. Topical treatment with injectable glucantime lasts up to 8 weeks.

Category

N/A

2**Description**

Intervention group: Patients in the second group are also treated with an intralesional injection of glucantime. The patient receives a topical injection of glucantime 0.5 to 1.5 cc per week per lesion; So that all around the lesion (one-millimeter ring around it) becomes white. Topical treatment with injectable glucantime lasts up to 8 weeks. In addition, patients were treated by a low-level laser using an 820 nm probe 3 times a week for a total of 10 sessions at the intensity of 48 J/cm² for 30 seconds and then at the intensity of 9.6 J/cm² for 2 minutes

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sedigheh Tahereh Clinic

Full name of responsible person

Ali Asilian

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Dermatology Department, Sedigheh Tahereh Clinic, Khoram Street, Isfahan. ,

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Isfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Ali Asilian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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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

There is no further 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