Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison Between the Effect of Nd: YAG Laser and Glucantime on Treatment of Cutaneous Leishmaniasis

Protocol summary

Summary

This study, which is performed as clinical experimentation, is regarding Leishmaniasis. The samples were selected from among the leishmaniasis patients who visited the 17 Shahrivar Hygiene and Treatment Center in Ahwaz. In the first session, two separate leishmanial injuries are specified on the patient's body. The two injuries are subjected to clinical examination. The rate of induration was determined and a score of 1 to 5 was assigned by the examiner (a dermatology assistant). Then each injury was treated using one of the following two methods: A: To one of the injuries, Meglumine antimony is injected using a 1 cc insulin syringe. The maximum injection amount in each session is 1-2 cc. The injection is repeated weekly until the complete improvement of the injury, with a maximum of 10 injections. B: The other injury is subjected to laser treatments (AlexandritLtroni, Nd-YAG, and flow index of 220 J). Treatment with Nd-YAG is repeated in 2-week intervals until complete improvement (no indurations). (Maximum 5 treatment sessions.) In every treatment session, each injury is photographed and the rate of in duration is assigned a score of 1 to 5 by the examiner. After 10 weeks from the start of the treatment, the treatments are stopped and the above information is registered again. Follow-up of the skin injuries is performed after improvement and 3 months later. In each follow-up session, the injury is examined with regards to the scar and PIH, and photographed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042911363N2**
Registration date: **2017-06-09, 1396/03/19**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-06-09, 1396/03/19

Registrant information

Name
Hannaneh Davoodzadeh
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Between the Effect of Nd: YAG Laser and Glucantime on Treatment of Cutaneous Leishmaniasis

Public title

Comparison Between the Effect of Nd: YAG Laser and Glucantime on Treatment of Cutaneous Leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Being 5 to 55 years of age; having at least two leishmanial injuries (leishmaniasis is defined as having a clinical injury according to Cutaneous leishmaniasis along with positive smear test regarding leishmanial body confirmed by a pathologist. Exclusion criteria:Being pregnant or nursing; receiving any prior treatments (including medical or cryotherapy or laser or other destructive methods).

Age

From **5 years** old to **55 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

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

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz, Iran

City

Ahvaz

Postal code

Approval date

2016-12-03, 1395/09/13

Ethics committee reference number

IR.AJUMS.REC.1395.540

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

Complete improvement of the injury

Timepoint

At the end of every session, 10 weeks after start of treatment, and 3 months after improvement

Method of measurement

Measuring the induration and the size of the injury

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 2: The other injury is subjected to laser treatments (AlexandritLtroni, Nd-YAG, and flow index of 220 J).

Category

Treatment - Other

2

Description

Intervention group 2: To one of the injuries, Meglumine antimony is injected using a 1 cc insulin syringe. The maximum injection amount in each session is 1-2 cc. The injection is repeated weekly until the complete improvement of the injury, with a maximum of 10 injections.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz 17th Shahrivar Center

Full name of responsible person

Mohammad Omidian

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz, Iran

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Dr Saaki Naader

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz, Iran

City
Ahvaz

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Maryam Jad Babai

Position
Dermatologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty