

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Clinical trial for the Comparison of the effect of PDL laser and injection of glucantime in the treatment of cutaneous lesions of leishmaniasis patients

Protocol summary

Summary

The goal of this study is to evaluate the effect of PDL laser versus the routine treatment with intralesional glucantime injection. Inclusion criteria is having at least 2 cutaneous lesion with positive smear. The patients who have been treated with any other method will be excluded from study. This is a not blind not randomized randomised clinical trial. The sample size is 19 patients with 38 cutaneous lesions. Each of the lesions will be treated with one of the two treatments. For one of the lesions, glucantime (vial 1gr/5cc) will be injected intralesional with insulin syringe. The interval between the injections will be one week until the lesion will be completely cured and maximum 10 injections will be done. The other lesion will be treated with PDL laser (N light, model A00-0159) with the setting of 7j/cm² fluence, and 5mm spot size. Laser therapy will be continued with 2 weeks interval, until complete cure of the lesion or maximum 4 sessions. The lesions will be assessed through photography and induration score (from 1 to 5) at the beginning and at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072018536N1**
Registration date: **2017-03-21, 1396/01/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-21, 1396/01/01

Registrant information

Name

Ehsan Omidian

Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 626 8737

Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-01-04, 1395/10/15

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial for the Comparison of the effect of PDL laser and injection of glucantime in the treatment of cutaneous lesions of leishmaniasis patients

Public title

Evaluation of PDL laser for the treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 5-55 years; having at least 2 leishmania lesion on the everywhere of body skin with positive direct smear for leishman body. Exclusion

criteria: Pregnancy; lactation; using any other treatments before the beginning of the study.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Not randomized

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

Ethics committee of Ahvaz Jondishapur University of Medical Sciences

Street address

Daneshgah sq, Ahvaz, Iran

City

Ahvaz

Postal code

15794-61357

Approval date

2014-04-23, 1393/02/03

Ethics committee reference number

Ajumsrec.1393.15

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

Induration index

Timepoint

Before the beginning of the study, Every 2 weeks for 10 weeks.

Method of measurement

Physical examination by dermatologist

Secondary outcomes

1

Description

Post inflammatory hyperpigmentation

Timepoint

Every 2 weeks for 10 weeks.

Method of measurement

Physical examination by dermatologist

Intervention groups

1

Description

Intervention group 1: For one of the lesions, glucantime (vial 1gr/5cc) will be injected intralesional with insulin syringe. The interval between the injections will be one week until the lesion will be completely cured and maximum 10 injections will be done.

Category

Treatment - Drugs

2

Description

Intervention group 2: The other lesion will be treated with PDL laser(N light, model A00-0159) with the setting of 7j/cm2 fluence, and 5cm spot size. Laser therapy will be continued with 2 weeks interval, until complete cure of the lesion or maximum 4 sessions.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Ehsan Omidian

Street address

Imam Khomeini hospital, Azadegan Blvd

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dr Radmanesh clinic

Full name of responsible person

Seyed Mohammad Radmanesh

Street address

Eastern 6 street, Kianpars, Ahvaz

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dr Radmanesh clinic

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 Jondishapur University of Medical Sciences

Full name of responsible person

Ehsan Omidian

Position

Dermatology resident

Other areas of specialty/work

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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