Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the therapeutic effect of IPL with wavelength spectrum effective on vascular lesions and intralesional Glucantime in treatment of patients with acute cutaneous leishmaniasis

Protocol summary

Study aim
determination of the therapeutic effect of IPL laser with effective wavelength spectrum for vascular lesions on active lesions of cutaneous leishmaniasis

Design
This study is a parallel controlled clinical trial on 30 cutaneous leishmaniasis patients. With a randomization software, laser treatment and treatment with intralesional injection of glucantime are randomly assigned to the patients.

Settings and conduct
Blinding is not done in this study. 26 patients with leishmaniasis who have a maximum lesion number of 3 and are refereed to Ghaem hospital in Mashhad enter the study. Follow-ups are carried out at intervals of 3 and 6 months after the first treatment session.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Cases with confirmed urban leishmaniasis based on clinical presentation and skin smear result, indication of topical treatment, maximum lesion number of 3, duration of the disease is less than 3 months, no laceration on the lesion. exclusion criteria: pregnancy, photosensitivity, positive Kobner test skin disease

Intervention groups
Intervention group: patients with acute urban leishmaniasis with less than 3-month treatment time will be placed under treatment with IPL laser device every 2 weeks (up to 6 sessions). The treatment of first session for the intervention group is carried out using laser Palomar system with 38-40 J / cm2 fluence. Afterwards, the parameters of the device in each session will be set aiming at creating purpura and ecchymorous. Control group: Patients with acute urban leishmaniasis will be treated with intralesional injection of glucantime weekly for up to 10 weeks.

Main outcome variables
diameter of lesion induration ; photography

General information

Reason for update
Completion of trial and changes in actual sample size, as well as extended treatments.

Acronym

IRCT registration information
IRCT registration number: **IRCT20140414017271N5**
Registration date: **2018-11-29, 1397/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-25, 1398/12/06**
Update count: **2**

Registration date
2018-11-29, 1397/09/08

Registrant information

Name
Yalda Nahidi

Name of organization / entity
department of dermatology, Ebne Sina St, Emam Reza hospital

Country
Iran (Islamic Republic of)

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+98 51 1802 2490

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nahidiy@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-15, 1397/06/24

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
2018-09-15, 1397/06/24
Actual recruitment end date
2019-05-02, 1398/02/12
Trial completion date
2019-12-05, 1398/09/14

Scientific title
Comparing the therapeutic effect of IPL with wavelength spectrum effective on vascular lesions and intralesional Glucantime in treatment of patients with acute cutaneous leishmaniasis

Public title
Therapeutic effect of laser on leishmaniasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Cases with confirmed urban leishmaniasis based on clinical presentation and skin smear result Indication for topical treatment Maximum lesion number of 3 Disease duration less than 3 months No damage to the lesion Informed consent to participate in the study
Exclusion criteria:
pregnancy photosensitivity positive Kobner test skin disease
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **26**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly divided into two groups based on the list of random numbers generated by a computer.
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 Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Approval date
2018-07-25, 1397/05/03
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.398

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
Photography of lesion
Timepoint
Photos are evaluated at each treatment session and then 3 and 6 months after the first treatment session.
Method of measurement
Camera

2

Description
diameter of lesion induration
Timepoint
Diameter of lesion induration is evaluated at each treatment session and then 3 and 6 months after the first treatment session.
Method of measurement
Caliper

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients with acute urban leishmaniasis with less than 3 months treatment time will be placed under treatment with IPL device every 2

weeks (up to 6 sessions)

Category

Treatment - Devices

2

Description

Control group: patients with acute urban leishmaniasis will be treated with intralesional injection of glucantime weekly for up to 10 weeks (11 sessions).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Imam Raza Hospital

Full name of responsible person

Zahra Tafazzoli

Street address

Ghaem Hospital, Ahmad Abad Avenue

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Tafazzoliz951@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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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

Zahra Tafazzoli

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Emam Reza hospital, Emam Reza Sq, Ebne-sina Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Yalda Nahidi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Yalda Nahidi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers at universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments