

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of Laser therapy on the healing of diabetic foot ulcers

Protocol summary

Study aim

Evaluation of the effectiveness of laser therapy on the healing of foot ulcers in diabetic patients

Design

clinical trial with a control group, with factorial groups, without blinding, randomized, on 60 patients. Excel random function was used for randomization.

Settings and conduct

30 Patients with diabetic ulcers underwent laser treatment in the hospital for 20 sessions for 30 minutes and the other 30 patients received only wound washing, dressings, and antibiotics.

Participants/Inclusion and exclusion criteria

Inclusion criteria included type 2 diabetes, a history of diabetic foot ulcer for at least one month, and patient consent to participate in the research project. Criteria for concomitant exclusion of other neurological diseases, infectious and discharged foot ulcers, Laser sessions for cosmetic or therapeutic purposes in the last trimester were the patient's dissatisfaction with participating in the research project

Intervention groups

This research was conducted in two groups. The first group underwent laser therapy intervention and simultaneous treatment of diabetic foot ulcer including daily rinsing with betadine, antibiotic treatment and the second group underwent only the usual treatment of diabetic foot ulcer including daily rinsing with betadine, antibiotic treatment and dressing.

Main outcome variables

The main variables include the diameter of the foot ulcer, the depth of the foot ulcer, neuropathy, which will be prevented from infection and amputation by laser treatment by reducing the depth and diameter of the foot ulcer.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048231N1**

Registration date: **2022-01-24, 1400/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-24, 1400/11/04**

Update count: **0**

Registration date

2022-01-24, 1400/11/04

Registrant information

Name

Sara Tabakhha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6657 3952

Email address

tabbakhhasara@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-08, 1400/08/17

Expected recruitment end date

2022-02-06, 1400/11/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Laser therapy on the healing of diabetic foot ulcers

Public title

Laser therapy on the healing of diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having type 2 diabetes History of at least one month of having a diabetic foot ulcer Patient consent to participate in the research project

Exclusion criteria:

Infectious foot ulcers with discharge Concurrent with other neurological diseases Laser sessions for cosmetic or therapeutic purposes in the last trimester Patient dissatisfaction with participating in the research project

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Number the names of patients referred to Imam Hossein Hospital who have diabetes and have diabetic foot ulcers and are willing to participate in the study from 1 to 60 And using the site www.random.org, which is a site for generating random numbers online, we will have two columns that contain 30 numbers randomly, we will select one column as the control group and one column as the patient.

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**

Ethic committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak Street, Tehran

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tehran

Province

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Postal code

1985717443

Approval date

2019-11-14, 1398/08/23

Ethics committee reference number

IR.SBMU.MSP.REC.1398.275

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

Type 2 diabetes

ICD-10 code**ICD-10 code description**

دیابت

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

Diabetic wound size before and after laser treatment

Timepoint

before and after laser treatment

Method of measurement

Using meters and centimeters

Secondary outcomes

empty

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

The patient group consisted of patients for 20 sessions of 30 minutes each time They underwent laser treatment every other day, in addition to the usual treatments such as washing and bandage, betadine and antibiotics.

Category

Treatment - Devices

2**Description**

Control group:In this group, patients with diabetic foot ulcers underwent only washing and bandage, betadine and antibiotics.

Category

Treatment - Drugs

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

Imam Hossein Hospital

Full name of responsible person

Sara Tabakhha

Street address

Madani Street, Imam Hosein Hospital

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Tehran

Province

Tehran

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1617763141

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziai

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School of Medicine, Shahid Beheshti University of
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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sara Tabakhha

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Resident

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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 more 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