Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
City
tehran
Province
Tehran
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Ali Ziai
Street address
School of Medicine, Shahid Beheshti University of Medical Sciences, Koodakyar St. Daneshjoo Blvd., Evin, Tehran, Iran
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193954719
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saziai@gmail.com
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
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Position
Resident
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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