Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Evaluation of LASER therapy in treatment of peripheral neuropathy of diabetic patients referred to Imam Hossein Hospital

Protocol summary

Study aim
Evaluation of LASER therapy in the treatment of peripheral neuropathy of diabetic patients
Design
A control trial with a control group, with parallel groups, without blinding, randomized, on 60 patients, will use the online random number generation site for randomization.
Settings and conduct
The subjects will be referred to Imam Hossein Hospital in Tehran and will undergo laser therapy in 12 sessions of15 minutes for each foot at intervals of one day. People undergoing laser treatment are unaware of the existence of the control group.
Participants/Inclusion and exclusion criteria
Inclusion criteria: peripheral neuropathy; satisfied with participating in this research. Exclusion criteria: other neurological diseases; people who underwent laser sessions for the purpose of recent cosmetic surgery.
Intervention groups
In the control group, patients with diabetic neuropathy do not receive laser therapy. Patients in the intervention group، receive laser therapy.
Main outcome variables
Reducing diabetic neuropathy in patients; reducing the complication of diabetic neuropathy such as amputation, improving the quality of life of diabetic patients with peripheral neuropathy.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201009048972N1**
Registration date: **2021-11-07, 1400/08/16**
Registration timing: **prospective**

Last update: **2021-11-07, 1400/08/16**
Update count: **0**
Registration date
2021-11-07, 1400/08/16

Registrant information
Name
sahar tavakkoli
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 3310 1479
Email address
sahartavakoli44@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-11, 1400/08/20
Expected recruitment end date
2021-12-11, 1400/09/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of LASER therapy in treatment of peripheral neuropathy of diabetic patients referred to Imam Hossein Hospital

Public title
Laser therapy in diabetic patient with neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic patients Peripheral neuropathy

Exclusion criteria:
No willingness to participate in the study; Other neurological diseases; People who underwent laser sessions for the purpose of recent cosmetic surgery.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
I will number the names of patients referred to the Imam Hossein hospital who have diabetes and are willing to participate in the research, and using an online random number generation site, I will select two groups of numbers as the control group and 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
Ethics committee of Shahid Beheshti University of Medical Science

Street address
No 193، Esmaiili Alley ، North Nabard Ave، Piroozi Ave

City
Tehran

Province
Tehran

Postal code
1765847145

Approval date
2019-06-24, 1398/04/03

Ethics committee reference number
IR.SBMU.MSP.REC.1398.277

Health conditions studied

1

Description of health condition studied
Peripheral neuropathy in diabetic patients

ICD-10 code
E11.40

ICD-10 code description
Type 2 diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Peripheral neuropathy in diabetic patients

Timepoint
Before and after laser therapy

Method of measurement
Michigan neuropathy screening test and monofilament test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Diabetic patients with peripheral neuropathy who undergo laser therapy with a wavelength between 650 to 810 nm three times a week for twelve sessions and each session for fifteen minutes per foot. The Noura instrument NIL IR105 laser device is made by Noura Layehnegar Company.

Category
Treatment - Other

2

Description
Control group: Diabetic patients with peripheral neuropathy who are being treated with common neuropathic drugs including gabapentin or B1 300 but will not receive laser treatment.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital in Tehran

Full name of responsible person
Sahar Tavakoli

Street address
No 193، Esmaiili Alley ، Nabard Ave، Piroozi Ave

City
Tehran

Province
Tehran

Postal code
1765847145
Phone
+98 21 3310 1479
Email
sahartavakoli44@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mostafa Rezaii Tavirani
Street address
sixth floor . University Headquarters Building No 2.Shahid Beheshti University of Medical Sciences and Health Services. - Next to Taleghani Hospital -- Parvaneh St. -Yemen St.Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9788
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Sahar Tavakoli
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sahar Tavakoli
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No 193، Esmaiili Alley، Nabard Ave، Piroozi Ave
City
Tehran
Province
Tehran
Postal code
1765847145
Phone
+98 21 3310 1479
Email
sahartavakoli44@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sahar Tavakoli
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No193. Esmaiili Alley. Dahom farvardin Ave. Piroozi Ave.
City
Tehran
Province
Tehran
Postal code
1765847145
Phone
+98 21 3310 1479
Fax
Email
sahartavakoli44@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sahar Tavakoli
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No193. Esmaiili Alley. Dahom farvardin Ave. Piroozi Ave.
City
Tehran
Province

Tehran

Postal code

1765847145

Phone

+98 21 3310 1479

Fax

Email

sahartavakoli44@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available