

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Tecar with Low Level Laser in improving neurological symptoms and Quality of life in lower extremity Peripheral Neuropathy in type2 diabetes patients

Protocol summary

Study aim

Comparison of the effect of tecar with low power laser after ten sessions of intervention and follow up three month after intervention on neurological symptoms and quality of life of peripheral neuropathy type2 diabetes

Design

intervention groups with parallel and randomized simple blocked groups in a double-blind manner on 15 people in each group

Settings and conduct

45 male and female patients typ2 diabetes will be performed in the physiotherapy clinic of the faculty of rehabilitation,shahid beheshti University of medical sciences,it will be done in a simple randomized block and double blind method,10sessions, 3 times a week.the evaluator and the therapist(researcher) are blinded

Participants/Inclusion and exclusion criteria

^Entry criteria: over50 years old, with at least 6 months of peripheral neuropathy symptoms of type2 diabetes,at least a score of 4 out of 10 on the pain visual analog scale, nerve conduction velocity tibial nerve< 40, body mass index< 30, and glycosylated hemoglobin<8.5 Non entry criteria: chronic kidney,lung diseases and peripheral vascular problems, presence of knee prosthesis and metal plate in the lower limb, pregnancy,addiction to drugs alcohol and smoking

Intervention groups

1- Tecar on + Laser on Italian New Age capacitor with a frequency of 250KHz and Power of 300 Watts and an output intensity <50%, is used Mustang 2000 Russian Laser, with two infrared wavelengths of 890 nanometer, out put power of 15 watts puls, frequency of 80 Hz and wavelength of 630nm red light, out put power 10 miliwatts, continious 2- Tecar on+ laser off As in the first group, the same methods are performed but with the Laser off 3- Laser on+ Tecar off As in the first group, the same methods are performed but with the Tecar off

Main outcome variables

Pain, Nerve conduction velocity, Tactile soles of the foot, Ankle Brachial Index, time up and go, Mishigan Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221105056408N1**

Registration date: **2022-12-22, 1401/10/01**

Registration timing: **prospective**

Last update: **2022-12-22, 1401/10/01**

Update count: **0**

Registration date

2022-12-22, 1401/10/01

Registrant information

Name

Mitra Javan Amoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4422 4357

Email address

javanamoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty	evaluation before and after the treatment is done by the main researcher.
Actual recruitment end date	Placebo
empty	Not used
Trial completion date	Assignment
empty	Parallel
Scientific title	Other design features
Comparison of the effect of Tecar with Low Level Laser in improving neurological symptoms and Quality of life in lower extremity Peripheral Neuropathy in type2 diabetes patients	The clinical trial has3 intervention groups with parallel groups and simple block randomization on 15 people in each group
Public title	Secondary Ids
Comparison the Effect of Tecar with Low power laser on peripheral neuropathy and quality of life in typ2 diabetes	empty
Purpose	Ethics committees
Treatment	1
Inclusion/Exclusion criteria	Ethics committee
Inclusion criteria:	Name of ethics committee
Age over 50 years Diagnosis of type2 diabetes by endocrinologist and neurologist Minimum pain score of 4 based on visual analog scale(VAS) Body mass index < 30 Nerve conduction velocity(Ncv) < 40 tibial motor nerve Controlled blood sugar for last three months(Glycosylated hemoglobin Hba1c < 8.5)	Ethics committee of shahid beheshti university of Medical Sciencesof medical sciences
Exclusion criteria:	Street address
The presence of symptoms of non diabetic neuropathy Systemic peripheral vascular involvement Pregnancy Patients with malignant tumors Chronic coronary artery,lung and kidney diseases Patients with pacemakers or mechanical insulin pumps Patient with knee joint teplacement and the presence of metal plaque in the lower limb Patients addicted to drugs, cigarettes and alcohol	No.10, Abazar4 alley, Moallem Street, Amol Town
Age	City
From 50 years old	Amol
Gender	Province
Both	Mazandaran
Phase	Postal code
N/A	4615798356
Groups that have been masked	Approval date
- Investigator - Outcome assessor	2021-04-11, 1400/01/22
Sample size	Ethics committee reference number
Target sample size: 45	IR.SBMU.RETECH.REC.1400.122
Randomization (investigator's opinion)	Health conditions studied
Randomized	1
Randomization description	Description of health condition studied
The randomization is a simple blocked method, we will have three groups of 15 people, each group will be assigned a code, and for each group, the code of the same group will be placed inside the closed envelope, and the patient will randoly choose an envelope	Peripheral neuropathy of the lower limb of type2 diabetes
Blinding (investigator's opinion)	ICD-10 code
Double blinded	ICD-10 code description
Blinding description	Primary outcomes
The main researcher will not divide the samples into two groups and this work will be done by the research assistant who is a physiotherapy expert. Also, the evaluator will not know about the grouping of people. Also, the intervention is done by another person and the	1
	Description
	pain
	Timepoint
	Before, after10 session and 3month after intervention
	Method of measurement
	Visual analogue scale (numerical)(VAS)
	2
	Description
	Nerve conduction velocity, tibial motor nerve
	Timepoint

Before, after 10 sessions and 3 months after intervention

Method of measurement

Electromyography device

3

Description

The feeling of tactile soles of the foot

Timepoint

Before, after 10 sessions and 3 months after intervention

Method of measurement

By Sims Weinstein 10g monofilament ten points on the soles of the feet will be evaluated

4

Description

Mishigan questionnaire

Timepoint

Before, after 10 sessions and 3 months after intervention

Method of measurement

The questionnaire has two parts, one part evaluates and records by evaluator and the other part fills by patient

5

Description

Ankle brachial index, it is the ratio of ankle systolic blood pressure to arm systolic blood pressure

Timepoint

Before, after 10 sessions and 3 months after intervention

Method of measurement

By digital sphygmomanometer

6

Description

Sensory Sural nerve amplitude

Timepoint

Before, after 10 sessions and 3 months after intervention

Method of measurement

Electromyography device

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention and after three months 10 sessions intervention

Method of measurement

Summary questionnaire of 26 questions of the World Health Organization

Intervention groups

1

Description

Intervention group: Tecar on + Laser off

Category

Treatment - Devices

2

Description

Intervention group: Tecar on + Laser on

Category

Treatment - Devices

3

Description

Intervention group: Laser on + Tecar off

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital, Tehran

Full name of responsible person

Mitra Javan Amoli

Street address

N.10, Abazar 4 alley, Moallem street, Amol Town

City

Amol

Province

Mazandaran

Postal code

4615798356

Phone

+98 11 4422 4357

Email

javanamoli@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Tehran, Shahid Chamran Highway, Yemen St., Shahid Arabi St., next to Taleghani Hospital, Shahid Beheshti University of Medical Sciences, Headquarters Building 2, 5th Floor, Deputy of research and technology

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Fax

+98 21 2243 9981

Email

Mpajouhesh@sbmu.ac.ir

Web page address

https://www.sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Deputy of researches and technology

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**

Academic

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Javan Amoli

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

N. 10, Abazar alley 4, Moallem street, Amol Town

City

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Phone

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Email

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Javan Amoli

Position

Associate Professor Physiotherapy

Latest degree

Master

Other areas of specialty/work

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Javan Amoli

Position

Associate Professor Physiotherapy

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All above will be published in article

When the data will become available and for how long

After the article publication

To whom data/document is available

Researchers and students in academic centers

Under which criteria data/document could be used

Other researchers and therapists in the reahabilitation and medical fild can use this study

From where data/document is obtainable

After the article publication, people can find the article by searching in internet and access the data

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

After requesting the documents, the person in charge of the research project must receive a written permission from the university and after obtaining the permission, send the documents,so summary will be sent about 6 months after the request for this data

Comments