Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effectiveness of Infrared radiation and Tecar Therapy with Infrared radiation on Peripheral Neuropathy in Patients with Type II Diabetes

Protocol summary

Study aim

Investigation of the Effect of Infrared radiation and Tecar Therapy with Infrared radiation on Peripheral Neuropathy in Patients with Type II Diabetes

Design

A Randomized, Single Blinds, Sham controlled clinical trial with Parallel Group Design of 24 Patients enrolled, and followed for six weeks

Settings and conduct

After evaluation of the intensity of pain, neurological disorders, tactile sensation of the feet and tibial nerve conduction velocity, patients were randomly divided into control and treatment groups. They were treated at the physiotherapy clinic of Rehabilitation faculty of Shahid Beheshti University of Medical Sciences. Patients were treated on separate days and were not aware of their placement in the treatment and control groups, so blinding was only applied to the participants of the study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:Age: 18-75; The least duration of illness affliction was more than six months; Patients have type II diabetes Mellitus with signs and Symtoms of mild(I) to moderate(II) Peripheral Neuropathy; Pain Intensity which was based on VAS (Visual Analog Scale) scores were more than three. Exclusion Criteria:Pregnancy; Diabetic Infectious Wound; Involvement of Cardiovascular system; Involvement of Respiratory system; To have Pace maker

Intervention groups

Treatment Group: Patients in the Treatment Group were treated with Infrared radiation and Tecar Therapy Control Group: Patients in the Control Group were treated with Infrared radiation and Sham Tecar Therapy

Main outcome variables

Intensity of pain based on visual analogue scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190726044337N1**
Registration date: **2019-10-20, 1398/07/28**
Registration timing: **retrospective**

Last update: **2019-10-20, 1398/07/28**
Update count: **0**

Registration date

2019-10-20, 1398/07/28

Registrant information

Name
Maryam Niajalili
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 13 4222 4593
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maryam_niajalili@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-08, 1398/01/19

Expected recruitment end date

2019-08-29, 1398/06/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effectiveness of Infrared radiation and Tecar Therapy with Infrared radiation on Peripheral Neuropathy in Patients with Type II Diabetes

Public title
The Effect of Tecar Therapy on Peripheral Neuropathy in Patients with Type II Diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age: 18-75 The least duration of illness affliction was more than six months Patients have type II diabetes Mellitus with signs and Symtoms of mild(I) to moderate(II) Peripheral Neuropathy Pain Intensity which was based on VAS (Visual Analog Scale) scores were more than three
Exclusion criteria:
Pregnancy Diabetic Infectious Wound Involvement of Cardiovascular system Involvement of Respiratory system To have Pace maker
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization: Patients were assigned a number according to the order of selection and were divided into treatment and control groups by sortition. The first pulled out number was assigned to the treatment group and the subsequent numbers were assigned to the two groups, respectively.
Blinding (investigator's opinion)
Single blinded
Blinding description
Only the Participants of the Study were Blinded and did not know which of the two treatment and control groups were assigned to them.That way, the Individuals in both groups were treated on separate days.
Placebo
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 Sciences
Street address
3th Floor, Medical school, Next to the Taleghani Hospital, Evin, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717434
Approval date
2018-12-18, 1397/09/27
Ethics committee reference number
IR.SBMU.RETECH.REC.1397.713

Health conditions studied

1

Description of health condition studied
Type II Diabetes
ICD-10 code
E11.4
ICD-10 code description
Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description
Intensity of pain
Timepoint
Before treatment, after ten session, Follow up for six weeks
Method of measurement
Base on visual analogue scale

Secondary outcomes

1

Description
Tactile sensation of feet
Timepoint
Before treatment, After ten session, Follow up for six weeks
Method of measurement
Monofilament 5.07/10 g

Intervention groups

1

Description
Intervention group: Patients in this group are treated with Infrared radiation (electromagnetic fields with 890

nanometers ,70-80 centimeters away from the surfaces of the foot) for 60 minutes and Capacitive Tecar Therapy (electromagnetic fields with 300-800 Kilohertz and intensity less than 50%) on Tibial nerve pathway with for 20 minutes in each session.Infrared radiation treatment is applied to dorsal, plantar, medial and lateral surface of the feet for twenty minutes and then, the passive electrode of tecar device is placed anterior surface of legs and its active electrode is moved along the tibial nerve pathway for twenty minutes in prone position.

Category

Rehabilitation

2

Description

Control group: Patients in this group are treated with Infrared radiation (electromagnetic fields with 890 nanometers , 70-80 centimeters away from the surfaces of the foot) for 60 minutes and Sham Capacitive Tecar Therapy (electromagnetic fields with 300-800 Kilohertz and Zero intensity) on Tibial nerve pathway with for 20 minutes in each session.Infrared radiation treatment is applied to dorsal, plantar, medial and lateral surface of the feet for twenty minutes and then, the passive electrode of tecar device is placed anterior surface of legs and its active electrode is moved along the tibial nerve pathway for twenty minutes in prone position; except that the current intensity is zero.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic of School of Rehabilitation Shahid Beheshti University of Medical Science

Full name of responsible person

Maryam Niajalili

Street address

No. 9, Kheyri Alley, Sardar-e Jangal Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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3th Floor, Medical school, Next to the Taleghani Hospital, Evin, Shahid Chamran Highway

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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

1

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

Maryam Niajalili

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Professor

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Person responsible for updating data

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

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

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

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