

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 Symptoms 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

Email address

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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 Symptoms 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

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

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

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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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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