

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Determining the effect of Intermittent Pneumatic Compression Device on balance of patients with diabetic neuropathy

Protocol summary

Summary

objectives and designs; Distal peripheral neuropathy is one of the causes of instability in diabetic patients. One of the supposed theories for diabetic peripheral neuropathy is reduction in blood flow secondary to pathologies of peripheral neural arterioles. Intermittent Pneumatic Compression, regarding to its effect on vessels hemodynamics and perfusion improvements, can improve the function of lower limb arterioles and increase neural nutrition. The aim of this study is investigation of the effect of Intermittent Pneumatic Compression on balance improvement and neuropathy signs, according to the role of diabetic neuropathy in balance dysfunction, in in type 2 diabetic patients with distal neuropathy. Setting and conduct; 39 patients with diabetes type 2 and neuropathy divided into intervention(20 patients) and control (19 patients) groups. The major inclusion criteria consisted of age between 40 to 75 and having type 2 diabetes and major exclusion criteria was cardiovascular disease. Intervention; The intervention group underwent 10 sessions of Intermittent Pneumatic Compression treatment that each sessions lasted 45 minutes. The pressure of Intermittent Pneumatic Compression device was 80 mmHg. variables; Both of groups, underwent clinical assessments including neuropathy questionnaires of Valk and Michigan, and balance tests of Romberg, Tandem stance and single leg stance, in first and final examination sessions. results showed significant improvement in neuropathy score according to Valk and Michigan neuropathy Questionnaires, in the intervention groups. The time of Tandem and single leg stance, also had significant increasing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013030312684N1**

Registration date: **2014-05-19, 1393/02/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-19, 1393/02/29

Registrant information

Name

Shirin Salek

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 82880

Email address

shirin.salek@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

university

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of Intermittent Pneumatic Compression Device on balance of patients with diabetic neuropathy

Public title

Determining the effect of Intermittent Pneumatic Compression Device on balance of patients with diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 5-15 years suffering from Diabetes Mellitus type 2; age between 40-75; Fasting Blood Glucose upper than 120 and lower than 250; Blood Pressure upper than 70 and lower than 140 mmHg; HbA1c 6.5-9%; symptoms of diabetic neuropathy; nerve conduction velocity of proneal and tibial nerve lower than 40 m/s; walking without aids; ability to communication; minimal Snellen chart of 20/40.
exclusion: non diabetic neuropathy; Alcoholism; cardiac disorders; Deep Vein Thrombosis; dysfunction of Central Nerves System; musculoskeletal disorders; Range Of Motion limitation of lower limbs; autonomic neuropathy; using drugs with effect on Central Nerves System.

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**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 Tarbiat Modares University

Street address

Chamran and Jalal Al-Ahmad Highway, Tehran, Iran

City

Tehran

Postal code

14115-111

Approval date

2013-07-06, 1392/04/15

Ethics committee reference number

2190/52

Health conditions studied**1****Description of health condition studied**

non insulin dependent diabetes

ICD-10 code

E11

ICD-10 code description

Diabetic polyneuropathy

Primary outcomes**1****Description**

functional balance

Timepoint

before and after the study

Method of measurement

Romberg, Single leg stance and Tandem stance

2**Description**

Dynamic balance

Timepoint

before and after the study

Method of measurement

Biodex system

3**Description**

Static balance

Timepoint

before and after the study

Method of measurement

Force Plate

Secondary outcomes**1****Description**

Vibration perception

Timepoint

before and after the study

Method of measurement

Diapason

Intervention groups**1****Description**

10 sessions intervention with Intermittent Pneumatic Compression device in intervention group

Category

Treatment - Devices

2

Description

without any intervention in control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Atieh Hospital

Full name of responsible person

Dr Mohammad-Reza Mohajeri-Tehrani

Street address

Phase 3, Shahrak Qods, Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Dr Mamouchehr Khan Nakhjavani

Street address

End of Keshavarz Blv, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tarbiat Modares University

Full name of responsible person

Dr Gholam- Reza Mosavi

Street address

Chamran and Jalal Al-Ahmad Highway, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tarbiat Modares University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Shirin Salek

Position

Msc student of Physical Therapy

Other areas of specialty/work

Street address

Chamran and Jalal Al-Ahmad Highway, Tehran, Iran

City

Tehran

Postal code

14115-111

Phone

+98 21 8288 3819

Fax

Email

shirinsalek@yahoo.com; shirin.salek@modares.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Shirin Salek

Position

Msc student of Physical Therapy

Other areas of specialty/work

Street address

Chamran and Jalal Al-Ahmad Highway, Tehran, Iran

City

Tehran

Postal code

14115-111

Phone

+98 21 8288 3819

Fax

+98 21 8800 6544

Email

shirinsalek@yahoo.com; shirin.salek@modares.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Shirin Salek

Position

Msc student of Physical Therapy

Other areas of specialty/work

Street address

Chamran and Jalal Al-Ahmad Highway, Tehran, Iran

City

Tehran

Postal code

14115-111

Phone

+98 21 8288 3819

Fax

+98 21 8800 6544

Email

shirinsalek@yahoo.com ;shirin.salek@modares.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty