Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Phone

+98 21 82880

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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
2190/52ر

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
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2

Recruitment center
Name of recruitment center
Emam Khomeini Hospital
Full name of responsible person
Dr Mamouchehr Khan Nakhjavani
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End of Keshavarz Blv, Tehran, Iran
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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
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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

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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