

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Investigating the effect of intermittent pneumatic compression therapy on the kinetic parameters of gait in diabetic patients with neuropathy

#### Protocol summary

##### Study aim

Investigating the effect of intermittent pneumatic compression therapy on the kinetic parameters of gait in diabetic patients with neuropathy

##### Design

In this study, we will have an intervention group and a control group that will be identical. The sample size of each group will be at least 15, and the applicants will be randomly divided into two groups using the table of random numbers.

##### Settings and conduct

At first, type 2 diabetic patients will enter the study according to the inclusion and exclusion criteria, and after primary assessments, they will receive intervention for 10 sessions, and then they will be evaluated and compared with the primary results. the location of the project will be in Karaj.

##### Participants/Inclusion and exclusion criteria

1- People with type 2 diabetes. 2- 5 to 15 years have passed their diabetes. 3- People in the age range of 40 to 75 years. 4- Fasting blood sugar should be 120-250 5- The patient's blood pressure should be at least 100/60 mmHg and maximum 40/140 mmHg. 6- HbA1c between 6/5-9%. 7 - People with symptoms of moderate diabetic sensory neuropathy. 8. To show neuropathy, Proneal and Tibial nerves motor NCV be lower than 40 m/s. 9- People have the ability to walk without the need for assistive devices. 10 - People have the ability to participate in the study and communication with the therapist. 11- People with independent life and visual acuity should prevail in the eyes at least in proportion to 20/40.

##### Intervention groups

The intervention group will undergo 10 sessions of intermittent pneumatic compression therapy for 45 minutes. During these 10 sessions, the control group will not receive any intermittent pneumatic compression therapy and balance training. only took their usual medications (including those that will not affect the vascular system).

#### Main outcome variables

Changes in the kinetic parameters of gait

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190417043299N2**

Registration date: **2020-04-27, 1399/02/08**

Registration timing: **prospective**

Last update: **2020-04-27, 1399/02/08**

Update count: **0**

##### Registration date

2020-04-27, 1399/02/08

##### Registrant information

##### Name

Seyed Ahmad Bagherian

##### Name of organization / entity

Tabriz university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3337 3207

##### Email address

a.bagherian@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-02, 1399/02/13

##### Expected recruitment end date

2020-05-20, 1399/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of intermittent pneumatic compression therapy on the kinetic parameters of gait in diabetic patients with neuropathy

**Public title**  
effect of intermittent pneumatic compression on diabetic neuropathy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Type 2 diabetic patients with 5 to 15 years disease duration Fasting blood sugar should be 120-250. The patient's blood pressure should be at least 100/60 mmHg and below 140/190 mmHg. Hb A1c between 6.5 - 9%. applicants have moderate diabetic sensory neuropathy symptoms. age between 40-75 years

**Exclusion criteria:**

Patients with non-diabetic neuropathy and rheumatoid patients. Patients who smoke, smoke hookah and drink alcohol. People with heart disease or have a history of orthopedic surgery. Patients with venous thrombosis. Patients with limited range of motion of the lower extremities. Patients with edema in the lower extremities.

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

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
A random numbers table will be used to randomize the grouping. In this way, the applicants to whom the odd numbers are assigned will enter the intervention group and the applicants to whom the even numbers will be assigned will enter the control group.

**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**

Committee of Ethics in Research at Tarbiat Modares university

**Street address**

Tarbiat Modares University, Jalal-Al-Ahmad St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713116

**Approval date**

2015-11-22, 1394/09/01

**Ethics committee reference number**

5747/52

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes mellitus

**ICD-10 code**

E11.40

**ICD-10 code description**

Type 2 diabetes mellitus with diabetic neuropathy, unspecified

## Primary outcomes

### 1

#### Description

Kinetic parameters of gait Clinical evaluation and comparison before and after treatment

**Timepoint**

Before intervention and after 10 treatment sessions

**Method of measurement**

Force plate device and evaluation of vibration sense by diapason

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After the primary assessments, the intervention group will undergo 10 treatment sessions by intermittent pneumatic compression . During this period, the group will also receive their usual medication.

**Category**

Rehabilitation

## 2

### Description

Control group: Control group: During these 10 sessions, the control group will not receive any intermittent pneumatic compression therapy or balance training and will only take their usual medications (except those that affect the vascular system).

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dr. Mahdi Dehghani specialized clinic

##### Full name of responsible person

Mahdi Dehghani Mohammad Abadi

##### Street address

خیابان شهید بهشتی، جنب ساختمان شهر کتاب، ساختمان پزشکان  
نور، طبقه ی ۴، واحد ۱۵

##### City

Karaj

##### Province

Alborz

##### Postal code

3144716458

##### Phone

+98 26 3421 6009

##### Email

mehdidehghani52@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tarbiat Modares University

##### Full name of responsible person

Yaaghoub Fath Allahi

##### Street address

The University of Tarbiat Modares, Jalal-Al-Ahmad St.

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713116

##### Phone

+98 21 8288 3101

##### Email

Res@modares.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Tarbiat Modares University

##### Proportion provided by this source

100

##### 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

The University of Tarbiat Modares

##### Full name of responsible person

Seyed Ahmad Bagherian

##### Position

Student

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

The university of Tarbiat Modares, Jalal-Al-Ahmad St.

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713116

##### Phone

+98 21 8288 3590

##### Fax

##### Email

a.bagherian@modares.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

The University of Tarbiat Modares

##### Full name of responsible person

Farid Bahrpeyma

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Physiotherapy

##### Street address

The University of Tarbiat Modares, Jalal-Al-Ahmad

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713116

##### Phone

+98 21 8288 3590

**Email**

bahrpeyf@modares.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

The University of Tarbiat Modares

**Full name of responsible person**

Seyed Ahmad Bagherian

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

The university of Tarbiat Modares, Jalal-Al-Ahmad St.

**City**

Tehran

**Province**

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**Postal code**

1411713116

**Phone**

+98 21 8288 3590

**Fax**

**Email**

a.bagherian@modares.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

All information can be shared after making the subjects unidentifiable.

**When the data will become available and for how long**

6 months after publication of results

**To whom data/document is available**

All individuals can use information about the results of the study.

**Under which criteria data/document could be used**

To treat diabetic patients and to carry out new research in this field, data can be used with unidentifying individuals of the study.

**From where data/document is obtainable**

They can contact the researcher by email They can meet the Physical Therapy Department of Tarbiat Modares University

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

The requestor should explain the cause of the need for the data clearly and if the reasons are convincing, the data will be available to him.

**Comments**