

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of aerobic training on neural conduction and glucose control in type-2 diabetic men with peripheral neuropathy.

#### Protocol summary

##### Summary

The aim of the present study was to examine the effect of aerobic training on neural conduction and glucose control in type-2 diabetic men with peripheral neuropathy. This is a non-blinded parallel-designed clinical trial in which eligible patients were randomly assigned into experimental or control groups. The inclusion criteria included being at the age of 30 to 60 years; type 2 diabetes; diabetes history for over 5 years; HbA1C more than 6.6%; diagnosed by a physician; abnormal electrodiagnostic examination confirming peripheral neuropathy. The exclusion criteria included type-1 diabetes; insulin therapy; exercising regularly and having a restriction for exercise participation. In this study, 32 participants from Shahid Mahalati and Emam Reza hospitals were randomly assigned into experimental or control groups. Exercise intervention included 20 to 45 minutes walking and running with 50 to 70 percent of heart rate reserve, three sessions per week during 12 weeks. Throughout the study course, participants in control group received no intervention and were asked to continue habitual physical activity. Before and 48h after the experimental period, body composition measurements and blood sampling for glucose analysis were performed. Moreover, nerve conduction studies (NCS) on sural, proneal and tibial nerves in lower limbs were performed. The primary outcomes included nerve conduction velocity and nerve action potential amplitude and the secondary outcomes included glucose and lipid profile indices.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017012032066N1**

Registration date: **2017-03-09, 1395/12/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-03-09, 1395/12/19

##### Registrant information

###### Name

Farhad Gholami

###### Name of organization / entity

Shahrood University of Technology

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41332395900

###### Email address

gholami-fa@shahroodut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Private

##### Expected recruitment start date

2015-06-05, 1394/03/15

##### Expected recruitment end date

2015-08-06, 1394/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of aerobic training on neural conduction and glucose control in type-2 diabetic men with peripheral neuropathy.

##### Public title

Effect of exercise on diabetic peripheral neuropathy.

##### Purpose

Health service research

## Inclusion/Exclusion criteria

Inclusion criteria: being at the age of 30 to 60 years; type 2 diabetes; diabetes history for over 5 years; HbA1C more than 6.6%; diagnosed by a physician; abnormal electrodiagnostic examination confirming peripheral neuropathy. Exclusion criteria: type-1 diabetes; insulin therapy; exercising regularly and having a restriction for exercise participation

## Age

From **30 years** old to **60 years** old

## Gender

Male

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **32**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Patients were randomly assigned into groups using random number table.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

##### City

Tabriz

##### Postal code

#### Approval date

2015-05-27, 1394/03/06

#### Ethics committee reference number

TBZMED.REC.1394.153

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic Polyneuropathy

## ICD-10 code

G63.2

## ICD-10 code description

Diabetic polyneuropathy (E10-E14 with common fourth character .4+)

## Primary outcomes

### 1

#### Description

Nerve conduction velocity

#### Timepoint

Before and after the intervention

#### Method of measurement

Using EMG system; in terms of meter/second

## Secondary outcomes

### 1

#### Description

Plasma glucose

#### Timepoint

Before and after intervention

#### Method of measurement

Using specific kit; in terms of miligram/desiliter

### 2

#### Description

Lipid profile

#### Timepoint

Before and after intervention

#### Method of measurement

Using specific kit; in terms of miligram/desiliter

### 3

#### Description

Glycosylated hemoglobin (HbA1c)

#### Timepoint

Before and after intervention

#### Method of measurement

Using specific kit; in terms of percent

## Intervention groups

### 1

#### Description

Control group: Without exercise intervention. Throughout the study period control group were asked to continue habitual physical activity.

#### Category

Lifestyle

### 2

#### Description

Intervention group: aerobic exercise training including walking or running for 20 to 45 minutes at the intensity

of 50% to 70% of heart rate reserve, 3 days a week, through 12 weeks.

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emam Reza hospital

**Full name of responsible person**

Farhad Gholami

**Street address**

Emam Reza hospital, Daneshgah Street, Tabriz.

**City**

Tabriz

**2**

**Recruitment center**

**Name of recruitment center**

Shahid Mahallati hospital

**Full name of responsible person**

Farhad Gholami

**Street address**

Shahid Mahallati hospital, Rah-Ahan Street, Tabriz.

**City**

Tabriz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Investigator

**Full name of responsible person**

Farhad Gholami

**Street address**

Shahrood University of Technology, Hafte Tir Square, Tehran Street, Shahrood.

**City**

Shahrood

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Investigator

**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**

Shahrood University of Technology

**Full name of responsible person**

Farhad Gholami

**Position**

Faculty member/ PhD

**Other areas of specialty/work**

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**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*