Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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+98 41332395900
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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

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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