

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effectiveness of balance exercise in comparison with aerobic exercise on electro diagnostic parameters in patient with diabetic peripheral neuropathy

Protocol summary

Study aim

Comparison of EMG-NCV characteristics between the two groups

Design

After giving the necessary explanations, written consent is obtained from the mentioned patients, and then they are treated with balance or aerobic exercises in one of the two groups in a simple random manner and in a block method.

Settings and conduct

This is randomized clinical trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria include diabetics patient between the ages of 30 and 65 who are able to stand and walk independently without any assistive devices, and Electrodiagnostic tests have confirmed the presence of diabetic Neuropathy. Exclusion criteria include people with diabetic foot ulcers, uncontrolled blood sugar, inner ear infection, neurological diseases (other than neuropathy) or other disorders of balance, a history of recurrent ankle sprains in the past year, severe pain It is a disturbance of balance and the presence of any disturbing factor of balance other than diabetic neuropathy.

Intervention groups

Diabetic patients are divided into two groups of balance and aerobic exercise. Before the intervention, patients are tested for EMG-NCV and then they are given balance or aerobic exercise 3 days a week for 8 weeks. After 8 week EMG-NCV tests are taken again from patients.

Main outcome variables

Comparison of emg-ncv characteristics in diabetic patients into two groups of balance and aerobic exercise

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039324N4**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Sirous Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4382 3476

Email address

s.azizi@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-17, 1400/09/26

Expected recruitment end date

2022-04-23, 1401/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of balance exercise in comparison with

aerobic exercise on electro diagnostic parameters in patient with diabetic peripheral neuropathy

Public title

Effectiveness of balance exercise in comparison with aerobic exercise on electro diagnostic parameters in patient with diabetic peripheral neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetics patient between the ages of 30 and 65 are able to stand and walk independently without any assistive devices, are able to walking independently without any assistive devices, electrodiagnostic tests have confirmed the presence of diabetic neuropathy

Exclusion criteria:

Diabetic ulcers in the legs, uncontrolled blood sugar, inner ear infection, neurological diseases (other than neuropathy) or other disorders of balance, history of recurrent ankle sprains in the past year, severe disturbing balance presence Any factor that disturbs the balance other than diabetic neuropathy

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to balance or aerobic exercise in one of two groups using block randomization. To randomly assign two groups with 33 participants in each group (66 patients in total), we use block randomization with different block sizes. The size of the blocks is a multiple of 3 and a divisor of 66 (3,6,9). Initially, the size of the blocks is randomly selected. Then for each block, different permutations are determined for the size of the equal group. Finally, one of the permutations is randomly selected. Random numbers are generated using a computer in an independent statistical unit.

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 mical university for the islamic republic of iran s Army

Street address

Imam Reza hospital, Etemad zade street, Fatemi street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411718546

Approval date

2021-05-15, 1400/02/25

Ethics committee reference number

IR.AJAUMS.REC.1400.025

Health conditions studied

1

Description of health condition studied

DIABETS

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

emg-ncv

Timepoint

Before intervention -8 weeks after intervention

Method of measurement

Using a emg-ncv machine

Secondary outcomes

empty

Intervention groups

1

Description

ntervention group 1 is treated with aerobic exercise in 24 sessions (3 days a week for 8 weeks).

Category

Treatment - Other

2

Description

Intervention group: Intervention group 2 is treated with

balance exercises in 24 sessions (3 days a week for 8 weeks).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Tehran

Full name of responsible person

Fatemeh Vashaei

Street address

Imam Reza hospital, Etemad zade street, Fatemi street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Artesh University of Medical Sciences

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

Artesh University of Medical Sciences

Full name of responsible person

Fatemeh Vashaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

f_vashaei@yahoo.com

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

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Position

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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