Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of three types of aerobic, resistance, and topical specialized exercises on glycemic indexes and neuropathy in diabetic patients

Protocol summary

Study aim
Comparison of the effect of three types of aerobic, resistive, and localized exercises on glycemic indexes and neuropathy in diabetic patients

Design
The clinical trial with three intervention groups, pragmatic, Single-blind, randomized

Settings and conduct
This study is conducted in the Diabetes Clinic of Vasei Hospital in Sabzevar. The evaluator is unaware of the grouping. Patients are randomly assigned to the intervention group 1, 2 and 3. The response to treatment is evaluated using Neuron-EMG-Micro device, Michigan neuropathy questionnaires, ABI device, tuning fork at the end of the second month after intervention for all three groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: FBS above 126 mg/dl; Having diabetes for 4-6 years. Exclusion criteria: Having autonomic neuropathy; non-diabetic neuropathy using drugs affecting the nervous and vascular systems; Having Cardiac or musculoskeletal problems precludes activity.

Intervention groups
Intervention group 1: Patients in this group perform resistance training for 8 weeks and 3 sessions per week including 10 minutes of warm-up, 40 minutes of core exercise, and 10 minutes of cool-down. Intervention group 2: Patients in this group perform aerobic exercises for 8 weeks and 3 sessions per week including 10 minutes warm-up, 45 minutes core exercise and 5 minutes cool-down. Intervention group3: Patients in this group perform specialized topical exercises in this group for 8 weeks and 5 days a week with a special protocol (flexion, extension, abduction, and adduction of hip and shoulder and flexion and extension of elbow and knee and little joints).

Main outcome variables
Fast Blood Sugar (FBS); Hemoglobin A1C(HbA1C); the severity of diabetic neuropathy; Limbs hypertension, sense of vibration; balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181006041252N19**
Registration date: **2019-12-17, 1398/09/26**
Registration timing: **retrospective**

Last update: **2019-12-17, 1398/09/26**
Update count: **0**

Registration date
2019-12-17, 1398/09/26

Registrant information

Name
Mohammad Sahebkar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 4401 8337

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-14, 1398/01/25

Expected recruitment end date
2019-12-16, 1398/09/25

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of three types of aerobic, resistance, and topical specialized exercises on glycemic indexes and neuropathy in diabetic patients

Public title
The effect of three types of aerobic, resistance, and topical specialized exercises in diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
FBS above 126 mg/dl or 2h blood glucose above 200 mg/dl Diabetic neuropathy Having diabetes for 4-6 years History of Metformin use for at least 2 years Start medication for diabetes
Exclusion criteria:
Having autonomic neuropathy, non-diabetic neuropathy Using drugs affecting the nervous and vascular systems Having Cardiac or musculoskeletal problems precludes activity
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is conducted based on a permutation block, Accordingly, 9 blocks were allocated to patients, in each block, 3 were from the following treatment groups A, B, and C. Eventually, after completion of the blocks, group A undergoes resistance training, group B undergoes aerobic training and group C undergoes topical specialized training.
Blinding (investigator's opinion)
Single blinded
Blinding description
Each person in the study will be assigned to the code 'A', 'B' or 'C' . only outcome assessor is unaware of the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
Street address
Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Approval date
2019-03-16, 1397/12/25
Ethics committee reference number
IR.MEDSAB.REC.1397.127

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy
ICD-10 code
E08.40
ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Fasting blood sugar (FBS).
Timepoint
At the beginning of the study (before the intervention) and 2 months after the start of the training program.
Method of measurement
Use of Luminescence quantitative and ELISA methods.

2

Description
Hemoglobin A1C
Timepoint
At the beginning of the study (before the intervention) and 2 months after the start of the training program.
Method of measurement
Use of Luminescence quantitative and ELISA methods.

3

Description
The severity of diabetic neuropathy
Timepoint
At the beginning of the study (before the intervention)

and 2 months after the start of the training program.

Method of measurement

Use of the Michigan Neuropathy Screening Instrument (MNSI).

Secondary outcomes

1

Description

The limbs blood flow

Timepoint

At the beginning of the study (before the intervention) and 2 months after the start of the training program.

Method of measurement

Ankle-Brachial Index (ABI) device

2

Description

Dynamic equilibrium

Timepoint

At the beginning of the study (before the intervention) and 2 months after the start of the training program.

Method of measurement

Neuron-EMG-Micro device

3

Description

The sense of vibration

Timepoint

At the beginning of the study (before the intervention) and 2 months after the start of the training program.

Method of measurement

Tuning fork device

4

Description

The sense of touch

Timepoint

At the beginning of the study (before the intervention) and 2 months after the start of the training program.

Method of measurement

Round bottom pin, cotton or brush

Intervention groups

1

Description

The first Intervention group: Patients in this group perform resistance training for 8 weeks and 3 sessions per week including 10 minutes of warm-up, 40 minutes of core exercise, and 10 minutes of cool-down.

Category

Treatment - Other

2

Description

The second intervention group : Patients in this group perform aerobic exercises for 8 weeks and 3 sessions per week including 10 minutes warm-up, 45 minutes core exercise and 5 minutes cool-down.

Category

Treatment - Other

3

Description

The third intervention group: Patients in this group perform specialized topical exercises in this group for 8 weeks and 5 days a week with a special protocol (flexion, extension, abduction, and adduction of hip and shoulder and flexion and extension of elbow and knee and little joints).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei hospital

Full name of responsible person

Mohammad Sahebkar

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Vasei Hospital, Asadabady Ave., Sabzevar Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Ghorat

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Drghorat@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Sahebkar

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Latest degree

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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

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

Not applicable