

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 51 4401 8337

Email address

sahebkar@medsab.ac.ir

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

Street address

Vasei Hospital, Asadabady Ave., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 8337

Email

vasei.h@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Ghorat

Street address

Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4401 8319

Email

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

Street address

Sabzevar University of Medical Sciences, Tohid Blvd.,
Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4401 8337

Fax

Email

Mohammad.sahebkar66@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Hamid Marefati

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Sabzevar University of Medical Sciences, Tohid Blvd.,
Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4401 8319

Fax

Email

h.marefati@yahoo.com

Person responsible for updating data

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

Street address

Sabzevar University of Medical Sciences, Tohid Blvd.,
Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4401 8337

Fax

Email

Mohammad.sahebkar66@yahoo.com

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