Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of effects of two types of aerobic and resistance training on sarcopenia indexes (SI) in diabetic patients

Protocol summary

Study aim
Determination of the effect of a period of aerobic and resistance training on sarcopenia indices in diabetic patients

Design
The clinical trial with two groups (intervention 1 and 2), pragmatic, single-blind, randomized.

Settings and conduct
This study is conducted to compare the effect of two types of aerobic and resistive exercises on sarcopenia indexes in diabetic patients the Diabetes Clinic of Vasei Hospital of Sabzevar. The evaluator is unaware of the grouping. Patients are randomized in the intervention group 1 and 2. The response to treatment is evaluated using sarcopenia indices at the end of the second month after intervention for both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 40 and 70 years, Patients with low physical activity based on Global Physical Activity. Questionnaire. (GPAQ) standard questionnaire, Metformin consumption for at least 2 years, Having diabetes for 4-6 years. Exclusion criteria: Patients with a high blood glucose of 250 mg/dl, Having cardiac or musculoskeletal problems precludes activity, Using drugs affecting the nervous and vascular systems.

Intervention groups
Intervention group 1: Patients in this group perform resistance training for 8 weeks and 3 sessions per week including 10 minutes warm-up, 40 minutes core exercise and 10 minutes cool-down. Intervention group 2: Patients in this group perform aerobic exercise for 8 weeks and 3 sessions per week including 10 minutes warm-up, 45 minutes core exercise and 5 minutes cool-down.

Main outcome variables
Determination of testosterone, sarcopenia index, and waist to hip ratio (WHR).

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181006041252N17**
Registration date: **2019-12-01, 1398/09/10**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-01, 1398/09/10**
Update count: **0**

Registration date
2019-12-01, 1398/09/10

Registrant information
Name
Mohammad Sahebkar
Name of organization / entity
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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 effects of two types of aerobic and resistance training on sarcopenia indexes (SI) in diabetic patients

Public title
Comparison of two types of aerobic and resistance training on on sarcopenia indexes (SI) in diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with low physical activity based on GPAQ standard questionnaire Metformin consumption for at least 2 years Having diabetes for 4 to 6 years Fasting blood glucose above 126 mg /dL Age between 40 and 70 years
Exclusion criteria:
Patients with a high blood glucose of 250 mg/dl Having cardiac or musculoskeletal problems precludes activity Using drugs affecting the nervous and vascular systems
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: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was conducted based on a permutation block by a statistical consultant using random allocation software and the output sequences A and B are available to the researcher, Accordingly,12 blocks were allocated to patients, in each block, 2 were from following groups, treatment group A and group B. Eventually, after completing the blocks, Group A and B were trained with resistance and aerobic exercises respectively. First, we determine all foursome modes in which half of the individuals are assigned to group A and the other half to group B. Then we assign one of the digits 1 to 6 to each of the foursome combinations (which includes six modes). In the next step, we must randomly select 20 blocks of four and write their combinations in succession. For this we have to make 20 samplings with replacement from a six-member community; 20 times, choose a random number between 1 and 6 and this process will continue until the end of the sampling and the difference between the two groups will not exceed a maximum of two (half the size of the block)
Blinding (investigator's opinion)
Single blinded
Blinding description
Each person will be assigned a study code A and B, which will only be known to the researcher of the type of groups. The evaluator 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.1397.131

Health conditions studied

1

Description of health condition studied
Diabetes mellitus
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

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

2

Description
Determine Sarcopenia Index (SI)
Timepoint
At the beginning of the study (before the intervention) and 2 months after the beginning of the training

program.

Method of measurement

(Serum Creatinine value/Cystatin C value) × 100. Use of Luminescence quantitative and ELISA methods to measure serum levels.

3

Description

Determination of Waist to hip ratio (WHR)

Timepoint

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

Method of measurement

Use of meters

Secondary outcomes

1

Description

Determination of 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

Determination of 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

Determination of 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

Rub round bottom pin, cotton or brush

4

Description

Determination of 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

Use of Ankle-Brachial Index (ABI) device

5

Description

Determination of body mass index

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 standard meters and scales

Intervention groups

1

Description

Intervention group 1: Patients in this group perform resistance training for 8 weeks and 3 sessions per week including 10 minutes warm-up, 40 minutes core exercise and 10 minutes cool-down.

Category

Treatment - Other

2

Description

Intervention group 2: Patients in this group perform aerobic exercise 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

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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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
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Position
Consultant
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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
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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available