

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Investigating the effects of combined aerobic-resistance exercise training on levels of Asprosin, CTRP1, and MG53 in men with type 2 diabetes

Protocol summary

Study aim

Determination of the effects of combined aerobic-resistance exercise training on levels of Asprosin, CTRP1, and MG53 in men with type 2 diabetes

Design

An experimental study with a control group, with parallel groups, no blinding, pragmatic, permuted block randomization, 25 samples, phase 3 trial.

Settings and conduct

This study will be conducted in the Neyshabur Diabetes Clinic. Patients will be randomly assigned to the intervention (combined aerobic-resistance exercise) and control groups. The response to treatment will be evaluated using Luminescence quantitative and ELISA methods for the study groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: No cardiovascular, musculoskeletal, and metabolic disorders that limit exercise, No high blood pressure, No regular exercise activity in the last 6 months, No smoking, Not having diabetic foot ulcers and not receiving insulin. Exclusion Criteria: Inability to perform exercises.

Intervention groups

Intervention group: The training group will undergo combined aerobic-resistance exercise training with distinct intensity for 12 weeks, three sessions a week. Each training session will include 5 to 10 minutes of warm-up, 45 minutes of resistance training, 30 minutes of aerobic training, respectively. Control group: control subjects also will perform their routine activities. In order to measure the biochemical variables, blood sampling will be performed after 12 hours of fasting and in two steps before the start of the training program and after 12 weeks. Subjects will be asked to do no severe activity for two days prior to blood sampling.

Main outcome variables

Determine the levels of Asprosin, CTRP1, and MG53

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041252N15**

Registration date: **2019-10-25, 1398/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-25, 1398/08/03**

Update count: **0**

Registration date

2019-10-25, 1398/08/03

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

2019-09-01, 1398/06/10

Expected recruitment end date

2019-12-01, 1398/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of combined aerobic-resistance exercise training on levels of Asprosin, CTRP1, and MG53 in men with type 2 diabetes

Public title
Effects of combined aerobic-resistance exercise training on levels of Asprosin, CTRP1, and MG53 in men with diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Lack of cardiovascular, musculoskeletal, and metabolic disorders limiting exercise
 Lack of high blood pressure
 Lack of regular exercise activity in the last 6 months
 Not receiving insulin
 No smoking
 Not having diabetic foot ulcers
Exclusion criteria:
 Inability to perform exercises

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: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be conducted based on a permutation block by a statistical consultant using random allocation software and the output sequences A and B will be available to the researcher. Accordingly, 6 blocks will be made, in each block, 2 for A treatment group, 2 for B treatment group. First, we will determine all modes in which two individuals assigned to group A and two to group B. Then we will assign one of the digits 1 to 6 to each block. In the next step, we will randomly select the order of 6 blocks. For this we will draw 6 times among cards inside a bag with replacement. For blinding the order, 24 envelopes are numbered, opaques, sealed and stapled, respectively, and code A or B will be placed inside the envelope according to the sequence and each patient will be allocated to the group based on the letter in the envelop.

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 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

2019-11-27, 1398/09/06

Ethics committee reference number

IR.MEDSAB.REC.1398.039

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Determine the levels of Asprosin

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the start of the training program

Method of measurement

Use of Luminescence quantitative and ELISA methods

2

Description

Determine the levels of CTRP1

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the start of the training program

Method of measurement

Use of Luminescence quantitative and ELISA methods

3

Description

Determine the levels of MG53

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the start of the training program

Method of measurement

Use of Luminescence quantitative and ELISA methods

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The training group will undergo combined aerobic-resistance exercise training with distinct intensity for 12 weeks, three sessions a week. Each training session will include 5 to 10 minutes of warm-up, 45 minutes of resistance training, 30 minutes of aerobic training, respectively. In order to measure the biochemical variables, the blood sampling will be performed after 12 hours of fasting and in two steps before the start of the training program and after 12 weeks. Subjects will be asked to do no severe activity for two days prior to blood sampling.

Category

Treatment - Other

2**Description**

Control group: control subjects also will perform their routine activities. In order to measure the biochemical variables, blood sampling will be performed after 12 hours of fasting and in two steps before the start of the training program and after 12 weeks. Subjects will be asked to do no severe activity for two days prior to blood sampling.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabetes Clinic of Neyshabour University of Medical Sciences

Full name of responsible person

Dr. Mehdi Zarei

Street address

Health Center No. 7, Shariati St., Neyshabour Town

City

Neyshabour

Province

Razavi Khorasan

Postal code

9318614139

Phone

+98 51 3858 4040

Email

Zarei.m8716@yahoo.com

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

Dr. Mehdi Zarei

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 1604

Email

Zarei.m8716@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Mehdi Zarei

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 1604

Email

Zarei.m8716@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Mehdi Zarei

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 1604

Email

Zarei.m8716@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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