Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Aspirosin, 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 Aspirosin, 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

sahebkarm@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, opaqued, 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