Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Investigating the effects of combined aerobic-resistance exercise training on levels of Chemerin and Omentin in men with type 2 diabetes

Protocol summary

Study aim
Determination of the effects of combined aerobic-resistance exercise training on levels of Chemerin and Omentin in men with type 2 diabetes

Design
Clinical trial with two groups (intervention and control), Parallel, Pragmatic, Randomized

Settings and conduct
This study will be conducted to evaluate the effects of combined aerobic-resistance exercise training on levels of Chemerin and Omentin in men with type 2 diabetes in the Diabetes Clinic of Vasey Hospital in Sabzevar. Patients will be randomly assigned to the intervention (combined aerobic-resistance exercise) and control group. The response to treatment is evaluated using Luminescence quantitative and ELISA methods for the study groups.

Participants/Inclusion and 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. Exclusion Criteria: Inability to perform exercises, Having regular sports activities rather than research 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 only perform their routine activities. In order to measure the biochemical variables, the blood sampling is performed after 12 hours of fasting and in two steps before the start of the training program and after 12 weeks. Subjects are asked to do no severe activity for two days prior to blood sampling.

Main outcome variables
Determine the levels of Chemerin and Omentin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181006041252N11**
Registration date: **2019-05-21, 1398/02/31**
Registration timing: **retrospective**

Last update: **2019-05-21, 1398/02/31**
Update count: **0**

Registration date
2019-05-21, 1398/02/31

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
2015-04-13, 1394/01/24

Expected recruitment end date
2015-06-14, 1394/03/24

Actual recruitment start date
2015-04-13, 1394/01/24

Actual recruitment end date
2015-06-14, 1394/03/24

Trial completion date

2015-06-14, 1394/03/24

Scientific title
Investigating the effects of combined aerobic-resistance exercise training on levels of Chemerin and Omentin in men with type 2 diabetes

Public title
Effects of combined aerobic-resistance exercise training on levels of Chemerin and Omentin in men with type 2 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

Exclusion criteria:
Inability to perform exercises Having regular sports activities rather than research 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: **24**
Actual sample size reached: **24**

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, 6 blocks were allocated to patients, in each block, 2 from A treatment group, 2 from the B treatment group were placed. Eventually, after completing the blocks group A was trained with combined aerobic-resistance exercise, Group B does not receive any special treatment (control). First, we determine all sixsome modes in which two individuals are assigned to group A and two to group B. Then we assign one of the digits 1 to 6 to each of the sixsome combinations (which includes thirty-six modes). In the next step, we must randomly select 6 blocks of six and write their combinations in succession. For this we have to make 6 samplings with replacement from a six-member community; 6 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)
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
2015-04-13, 1394/01/24

Ethics committee reference number
IR.MEDSAB.REC.1394.2

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 chemerin

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 level of omentin

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 is performed after 12 hours of fasting and in two steps before the start of the training program and after 12 weeks. Subjects are asked to do no severe activity for two days prior to blood sampling.

Category

Treatment - Other

2

Description

Control group: control subjects also only perform their routine activities. In order to measure the biochemical variables, the blood sampling is performed after 12 hours of fasting and in two steps before the start of the training program and after 12 weeks. Subjects are 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 Sabzevar University of Medical Sciences

Full name of responsible person
Dr. Mehdi Zarei

Street address
Vasei Hospital, Tohid Blvd., 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
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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

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Person responsible for updating data

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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