

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of 12 weeks of single and combined aerobic exercise and ketogenic diet control on improving RBP4, FABP5, SFRP5 levels and metabolic risk indices in middle-aged men with metabolic syndrome

Protocol summary

Study aim

the effect of 12 weeks of aerobic exercise with ketogenic diet on plasma levels of retinol-binding protein 4 (RBP4), fatty acid-binding protein 5 (FABP5), and secretory adipocaine associated with Friesland 5 protein (SFRP5) resistance, Insulin and metabolic risk indicators in middle-aged men with metabolic syndrome.

Design

A randomized controlled clinical trial with parallel groups, single-blind, randomized to 60 subjects, we use the restricted randomization method randomization of block type.

Settings and conduct

The study will be conducted at the Shahid Madani University of Azerbaijan. Laboratory tests before and after 12 weeks of exercise and dietary control will be performed in a single-blind manner.

Participants/Inclusion and exclusion criteria

Being in the middle age range of 60-40 years, Middle-aged men with type 2 diabetes mellitus (T2DM) , Diagnosis of hypertensive status , body mass index with a score of more than 30 and waist circumference with a score of more than 102 cm, Having dyslipidemia

Intervention groups

Aerobic exercise group for 12 weeks / three sessions per week, ketogenic diet control for 12 weeks, combination of aerobic exercise and ketogenic diet control for 12 weeks and control group without exercise and ketogenic diet control

Main outcome variables

Measurement of RBP4, FABP5, SFRP5 levels and metabolic risk indices

General information

Reason for update

Acronym

MetS

IRCT registration information

IRCT registration number: **IRCT20180724040579N3**

Registration date: **2021-06-09, 1400/03/19**

Registration timing: **prospective**

Last update: **2021-06-09, 1400/03/19**

Update count: **0**

Registration date

2021-06-09, 1400/03/19

Registrant information

Name

Asgar Iranpour

Name of organization / entity

University of Mohaghegh Ardebili

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 12 weeks of single and combined aerobic exercise and ketogenic diet control on improving RBP4, FABP5, SFRP5 levels and metabolic risk indices in middle-aged men with metabolic syndrome	
Public title	effect of aerobic training with ketogenic diet on insulin resistance and metabolic risk indices in middle-aged men with metabolic syndrome
Purpose	Health service research
Inclusion/Exclusion criteria	Inclusion criteria: Being in the middle age range of 60-40 years Middle-aged men who have been diagnosed with type 2 diabetes mellitus (T2DM) for the past 24 months, according to criteria published in 1999 by the World Health Organization (WHO) in the range of 7 mmol / L or 126 Mg / dL and above) Middle-aged men with type 2 diabetes who use oral hypoglycemic drugs without the need for insulin for survival Diagnosis of hypertensive status (blood pressure levels equal to or greater than 140/90 mm Hg) Middle-aged men with general obesity (body mass index with a score of more than 30) and central (waist circumference with a score of more than 102 cm) Having dyslipidemia Exclusion criteria: Cardiovascular diseases Thyroid disease Liver and kidney diseases
Age	From 40 years old to 60 years old
Gender	Male
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, we use the restricted randomization method randomization of block type. In this four-group experiment, We will have consisted of 12 blocks (including 3 participants in the aerobic exercise intervention group, 3 participants in the ketogenic diet control intervention group, 3 participants in the combined aerobic exercise intervention and ketogenic diet control intervention group and 3 participants in the control group).
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 Tabriz University of Medical Sciences Street address Central Building of University of Medical Sciences,Golgasht St, Azadi St, Tabriz Town City Tabriz Province East Azarbaijan Postal code 5166616471 Approval date 2020-12-14, 1399/09/24 Ethics committee reference number IR.TBZMED.REC.1399.880
Health conditions studied	1 Description of health condition studied Metabolic syndrome ICD-10 code E88.81 ICD-10 code description Metabolic syndrome
Primary outcomes	1 Description Changes in RBP4, FABP5, SFRP5 levels and metabolic risk indices Timepoint Before and after 12 weeks of exercise and diet control Method of measurement Using laboratory kits
Secondary outcomes	empty
Intervention groups	1 Description Control group: without performing aerobic exercise and ketogenic diet control for 12 weeks Category N/A

2

Description

Intervention group: Aerobic exercise for 12 weeks / 3 sessions per week / 40-40 minutes per session

Category

Diagnosis

3

Description

Intervention group: Ketogenic diet control for 12 weeks

Category

Diagnosis

4

Description

Intervention group: Combining aerobic exercise for 12 weeks / 3 sessions per week / 40-60 minutes per session and ketogenic diet control for 12 weeks

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Azarbaijan Shahid Madani University

Full name of responsible person

Bahloul Ghorbanian

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Shahid Madani University of Azerbaijan, 35 km Tabriz-Maragheh Road, Tabriz, EastAzarbaijan Province

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Sponsors / Funding sources

1

Sponsor

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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

Azarbaijan Shahid Madani University

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

Azarbaijan Shahid Madani University

Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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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

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

Data Dictionary

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