Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of eight weeks aerobic, resistance, and combined exercises on plasma Irisin levels, insulin resistance and lipid profiles among obese women with metabolic syndrome

Protocol summary

Study aim
Compare effects of eight weeks aerobic, resistance, and combined exercises on plasma Irisin levels, insulin resistance and lipid profiles among obese women with metabolic syndrome

Design
Clinical trials with control group, with parallel groups, randomized

Settings and conduct
This study was conducted from February 2016 on 60 obese women with MetS. The study population comprised of women with metabolic syndrome (using simple random sampling) who were visiting public clinic (Emam Reza Clinic) running by Shiraz University of Medical Sciences. Literate participants read and signed informed consent, and verbal consent was obtained from illiterate patients.

Participants/Inclusion and exclusion criteria
60 Female Metabolic Syndrome/ Having at least 3 components of metabolic syndrome,Women 45-60 years old,No history of any specific disease (cancer, diabetes, cardiovascular problems, Skeletal-muscular / diagnosed with any history of any specific disease (cancer, diabetes, cardiovascular problems, Skeletal-muscular

Intervention groups
1- Aerobic training group 2- Resistance training group 3- Combined training group (aerobic-resistance) 4- Control group

Main outcome variables
Irisin / Glucose / Insulin / Insulin resistance / Cholesterol / Triglyceride

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180806040721N2**
Registration date: **2018-10-20, 1397/07/28**
Registration timing: **retrospective**

Last update: **2018-10-20, 1397/07/28**
Update count: **0**

Registration date
2018-10-20, 1397/07/28

Registrant information

Name
Roghayeh Koroni

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-12-01, 1395/09/11

Expected recruitment end date
2017-01-23, 1395/11/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of eight weeks aerobic, resistance, and combined exercises on plasma Irisin levels, insulin resistance and lipid profiles among obese women with

metabolic syndrome

Public title
The effects of eight weeks aerobic, resistance, and combined exercises on plasma Irisin levels, insulin resistance and lipid profiles among obese women with metabolic syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having at least 3 components of metabolic syndrome Women 45-60 years old No history of any specific disease (cancer, diabetes, cardiovascular problems, Skeletal-muscular problems)
Exclusion criteria:
diagnosed with history of any specific disease (cancer, diabetes, cardiovascular problems, Skeletal-muscular problems)
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
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
Shiraz University of Medical Sciences Ethics Committee
Street address
Eram Street
City
Shiraz
Province
Fars
Postal code
159/535121
Approval date
2018-07-02, 1397/04/11
Ethics committee reference number
IR.SHUMS.REC.1397.279

Health conditions studied

1

Description of health condition studied
Metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

2

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

Primary outcomes

1

Description
Irisin
Timepoint
measurement at the beginning of the study (before the intervention) and 2 months after the intervention
Method of measurement
Measurement Plasma Irisin Level Using Elis Kit Made in Germany.

Secondary outcomes

1

Description
Glocose
Timepoint
At the beginning of the study (before the intervention) and two months after the intervention began
Method of measurement
fasting blood glucose (glucose oxidase) measured

2

Description
Insulin
Timepoint
At the beginning of the study (before the intervention) and two months after the intervention began
Method of measurement
The level of insulin was measured by ELISA

3

Description

Triglyceride

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention began

Method of measurement

triglyceride (PAP-GPO / lipase) measured

Intervention groups

1

Description

Intervention group first: Aerobic training group En. Participants of this group performed their activities using treadmill or bicycle three times per week (on non consecutive days). Time of exercise was increased from 20 minutes per session (at 60% of maximum heart rate) to 60 minutes (at 75% of maximum heart rate) per session. Heart rate was regularly determined by the monitor's treadmill or cycle ergometers. Required heart rate was calculated by the Karvonen formula

Category

Treatment - Devices

2

Description

Intervention group second: Resistance training group En. Resistance training group This program was performed on different weight machines. Correct training techniques were instructed and supervised by professional trainers. The protocol was started on 2 days of the week during the first month and was increased to 3 non-consecutive days per week. Training was started during weeks 1 and 2 with intensity 60% onerepetition maximum (1RM) and was progressed to intensity 75-80% 1RM. The number of sets was 1-2 during the first month. This program included 10 different exercises for upper and lower body. Participants performed 3 sets of 8-10 repetitions (with a 90- 120 s rest between sets) of the following exercises: bench press, seated row, shoulder press, chest press, lateral pulldown, abdominal crunches, leg press, leg extension, triceps pushdown and seated bicep curls

Category

Treatment - Devices

3

Description

Intervention group third: Combined training group (aerobic-resistance) En. Combined training group (aerobic-resistance) The subjects of this group did the aerobic exercise plus resistance training programs 3 times a week. After a warm-up stage, they worked for 20-30 minutes on a treadmill or bicycle plus 2 sets of each of 8 exercises with 8-10 repetitions on weight machines

Category

Treatment - Devices

4

Description

control group: control group .En control group: control group A group that did not have any training intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Clinic affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Dianatinasab Mostafa

Street address

Motahhari Street

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Shiraz

Province

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159-535121

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz 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?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dianatinasab Mostafa

Position

Epidemiologist

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

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Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Position

Epidemiologist

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dianatinasab Mostafa

Position

Epidemiologist

Latest degree

Master

Other areas of specialty/work

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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

Disagreement with contractors to share their profile and data

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable people.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Only scholars working in academic institutions

Under which criteria data/document could be used

Only numerical analysis is allowed.

From where data/document is obtainable

Mostafa Dianti Install with Email Address: dianatinasab@sums.ac.ir

What processes are involved for a request to access data/document

Two months later, the researchers arrived.

Comments