

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Pilates Training with Resveratrol on Serum Levels of Inflammatory Indices, Oxidative Stress and Endoplasmic Reticulum Stress in Middle-Aged Obese Women

Protocol summary

Study aim

The aim of this study is to compare the effect of Pilates training, resveratrol, and their combination on the serum levels of inflammatory indices, oxidative stress, and endoplasmic reticulum stress in middle-aged obese women.

Design

This clinical trial study with a control group, will be conducted in phase 3 on 40 middle-aged obese women who are randomly selected. To place people in each group, Simple randomization by random allocation rule (balloting container and separate papers) is used.

Settings and conduct

Intervention Research, Karaj City, the research site is Sports Club. In this research, people who work with subjects are blinded. Since the exercise training did not have the ability to be blinded, the present study was performed in an unblinded manner. However, supplementation was blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being obese (Body mass index above 30), the Age range of 35-50 years, having an Inactive lifestyle (exercising less than 1 hour per week), and being willing to participate in the study. Exit criteria: not taking supplements and not doing training, and feeling the risk of doing the training.

Intervention groups

Control group: This group receives 500 mg starch tablets as a placebo during the intervention period. Training group: For 8 weeks, three sessions/weeks (20 to 40 minutes) training with an intensity of 14-16 on the ratings of perceived exertion. Resveratrol group: this group receives a tablet of 500 mg of resveratrol orally daily. Training+Resveratrol group: In this group the Simultaneous intervention, training, and Resveratrol, will treat with the same protocol described in the previous part.

Main outcome variables

Glucose-Regulated Protein 78 (GRP78), Tribbles homologue 3 (TRB3), Sestrin-2, Lipocalin-2, Malondialdehyde, Glutathione peroxidase and Insulin resistance index (HOMA-IR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140415017288N11**

Registration date: **2023-03-13, 1401/12/22**

Registration timing: **prospective**

Last update: **2023-03-13, 1401/12/22**

Update count: **0**

Registration date

2023-03-13, 1401/12/22

Registrant information

Name

Ahmad Abdi

Name of organization / entity

Ayatollah Amoli Branch, Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 11 4321 7126

Email address

a.abdi@iauamol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-05-10, 1402/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Pilates Training with Resveratrol on Serum Levels of Inflammatory Indices, Oxidative Stress and Endoplasmic Reticulum Stress in Middle-Aged Obese Women

Public title
Effect of Training and Resveratrol on Middle-Aged Obese Women

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Being obese (Body mass index above 30). Age range 35-50 years. Inactive lifestyle (exercise less than 1 hour per week) Being willing to participate in the study.
Exclusion criteria:
Diagnosis of other underlying diseases. Allergy to supplement use. Inability to do exercise training. Use of anti-inflammatory drugs.

Age
From **35 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **10**
Middle-Aged Obese Women

Randomization (investigator's opinion)
Randomized

Randomization description
In this research, subjects are selected by Simple randomization by the random allocation rule. After determining the sample size (40 people), numbers 1 to 4 are written on 40 small separate papers (10 sheets of paper for each number) and placed in a container. Number 1 is for the Placebo Control Placebo (C), number 2 is for the Pilates Training (PT), number 3 is for the Resveratrol (RSV) group and number 4 is for the Pilates Training-Resveratrol (PTRSV). Then each sheet of paper is randomly taken out by the subjects and placed in the intervention or placebo groups, respectively.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University - Ayatollah Amoli Branch

Street address

Islamic Azad University, Ayatollah Amoli branch, Komdareh village, km 5 of the old Amol-Babol road.

City

Amol

Province

Mazandaran

Postal code

678

Approval date

2023-01-29, 1401/11/09

Ethics committee reference number

IR.IAU.AMOL.REC.1401.117

Health conditions studied

1

Description of health condition studied

Middle-Aged Obese Women

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Glucose-Regulated Protein 78 (GRP78)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

2

Description

Tribbles homologue 3 (TRB3)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

3

Description

Sestrin-2
Timepoint
Before and after the protocol
Method of measurement
Biochemical and laboratory methods

4

Description
Lipocalin-2 (LCN2)
Timepoint
Before and after the protocol
Method of measurement
Biochemical and laboratory methods

5

Description
Malondialdehyde (MDA)
Timepoint
Before and after the protocol
Method of measurement
Biochemical and laboratory methods

6

Description
Glutathione peroxidase (GPx)
Timepoint
Before and after the protocol
Method of measurement
Biochemical and laboratory methods

7

Description
Insulin resistance index (HOMA-IR)
Timepoint
Before and after the protocol
Method of measurement
Biochemical, laboratory and formula methods

Secondary outcomes

empty

Intervention groups

1

Description
Control group: This group receives a 500 mg starch tablets as a placebo during the 8-week intervention period.
Category
Placebo

2

Description
Intervention group 1: Training group (in this group for eight-week, three session/weeks, the training start with 10 min warming and then 20 to 40 min training with an

intensity of 14-16 ratings of perceived exertion. Also, this group receives 500 mg starch tablets as a placebo during the 8-week intervention period).

Category
Treatment - Other

3

Description
Intervention group 2: Resveratrol supplement group (this group receives a tablet of 500 mg of Resveratrol orally daily). طبقه بندی.
Category
Treatment - Other

4

Description
Intervention group 3: Training+ Resveratrol supplementation group (In this group the Simultaneous intervention, training and Resveratrol supplementation, will treat with the same protocol that describe at the previous part).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Amoli Branch, Islamic Azad University
Full name of responsible person
Ahmad Abdi
Street address
Islamic Azad University, Ayatollah Amoli branch, Komdareh village, km 5 of the old Amol-Babol road.
City
Amol
Province
Mazandaran
Postal code
678
Phone
+98 11 4321 7124
Fax
+98 11 4321 7009
Email
a.abdi@iauamol.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Asieeh Abbassi Dalooi
Street address
Islamic Azad University, Ayatollah Amoli branch,

Komdareh village, km 5 of the old Amol-Babol road.

City

Amol

Province

Mazandaran

Postal code

678

Phone

+98 11 4321 7124

Fax

+98 11 4321 7009

Email

abbasi.dalooi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad 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

Islamic Azad University

Full name of responsible person

Ahmad Abdi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Islamic Azad University, Ayatollah Amoli branch,
Komdareh village, km 5 of the old Amol-Babol road.

City

Amol

Province

Mazandaran

Postal code

678

Phone

+98 11 4321 7124

Fax

+98 11 4321 7009

Email

a.abdi@iauamol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza Barari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Islamic Azad University, Ayatollah Amoli branch,
Komdareh village, km 5 of the old Amol-Babol road.

City

Amol

Province

Mazandaran

Postal code

678

Phone

+98 11 4321 7126

Email

alireza54.barari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ahmad Abdi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Islamic Azad University, Ayatollah Amoli branch,
Komdareh village, km 5 of the old Amol-Babol road.

City

Amol

Province

Mazandaran

Postal code

678

Phone

+98 11 4321 7124

Email

a.abdi@iauamol.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcomes will be shared.

When the data will become available and for how

long

Since 2023

To whom data/document is available

All researchers

Under which criteria data/document could be used

If people email the person responsible for the plan, they can get the desired documents in the form of a file.

(a.abdi58@gmail.com-09113001960)

From where data/document is obtainable

People can apply for documents through email.

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

Maximum one week

Comments