

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Preventive effects of Exercise Training and Salvia officinalis on Inflammation and Insulin Resistance in Postmenopausal Women

Protocol summary

Study aim

The aim of this study is to compare the effect of aerobic exercise, Salvia officinalis, and their combination on Inflammation and Insulin Resistance in Postmenopausal Women.

Design

This clinical trial study with a control group and a blind strain will be conducted in phase 3 on 32 postmenopausal women who are randomly selected. For randomization, Simple randomization by random allocation rule is used. The sample size is calculated using GPower software. After selection, the subjects are randomly divided into four groups: Placebo Control (C), Aerobic Training (AT), Salvia officinalis (So), and Training-Salvia officinalis (ATSo).

Settings and conduct

Intervention Research, Amol City, The research site is Hejab Sports Club, which has already been coordinated. In this research, people who work with subjects are blinded.

Participants/Inclusion and exclusion criteria

Being menopausal, having the Age range of 50-65 years, inactive lifestyle (exercise less than 1 hour per week), Not taking medicine in the last 6 months, and being willing to participate in the study.

Intervention groups

Control group: in this group we have not had any intervention during 8 weeks and will consider this group as a placebo. Training group (This group performs the aerobic exercise with an intensity of 40-80% of the maximum reserve heart rate for 8 weeks, three sessions a week). Salvia officinalis supplement group (this group receives three tablets of 100 mg So orally daily). Training+ Salvia officinalis supplementation group (In this group the Simultaneous intervention, training, and Salvia officinalis supplement will treat with the same protocol described in the previous part).

Main outcome variables

Inflammatory indexes such as Tumor Necrosis Factor- α .

Interleukin-10; Interleukin-12; Fasting Glucose; Fasting Insulin and Insulin Resistance Index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140415017288N9**

Registration date: **2023-02-03, 1401/11/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-03, 1401/11/14**

Update count: **0**

Registration date

2023-02-03, 1401/11/14

Registrant information

Name

Ahmad Abdi

Name of organization / entity

Ayatollah Amoli Branch, Islamic Azad University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Preventive effects of Exercise Training and Salvia officinalis on Inflammation and Insulin Resistance in Postmenopausal Women

Public title
Effect of Exercise and Salvia officinalis on Postmenopausal Women

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 being menopausal Age range 50-65 years Inactive lifestyle (exercise less than 1 hour per week) Not taking medicine in the last 6 months. Being willing to participate in the study.
Exclusion criteria:
 Supplement use. Diagnosis of other diseases during the implementation of the protocol. Not taking Salvia officinalis. Use of estrogen and other androgens and steroids that affect estrogen receptors.

Age
From **50 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
 Target sample size: **32**
 More than 1 sample in each individual
 Number of samples in each individual: **8**
 Postmenopausal 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 (32 people), numbers 1 to 4 are written on 32 small separate papers (8 sheets of paper for each number) and placed in a container. Number 1 is for the Placebo Control group (C), number 2 is for the Aerobic Training Group (AT), number 3 is for the Salvia Officinalis group (So) and number 4 is for the Training-Salvia Officinalis (ATSo). 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)
Single blinded

Blinding description
 All the study groups received the supplement in sealed packages that were coded. Coding is done by the researcher and the subjects do not know about it. The Salvia officinalis (So) and Training-Salvia Officinalis (ATSo) receive three 100 mg tablets of So for eight weeks. Placebo Control (C), and Aerobic Training (AT)

groups receive a placebo in the same pharmacological presentation. Starch is used as a placebo.

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 - Marvdasht Branch
Street address
 3 km of Marvdasht-Persepolis Boulevard, Islamic Azad University, Marvdasht Branch
City
 Marvdasht
Province
 Fars
Postal code
 13119-73711

Approval date
2022-11-26, 1401/09/05

Ethics committee reference number
IR.IAU.M.REC.1401.032

Health conditions studied

1

Description of health condition studied
Postmenopausal Women

ICD-10 code
Z79.890

ICD-10 code description
Postmenopausal

2

Description of health condition studied
Insulin resistance

ICD-10 code
R73.02

ICD-10 code description
Impaired glucose tolerance (oral)

Primary outcomes

1

Description
Tumor Necrosis Factor Alpha

Timepoint
Before and after the protocol

Method of measurement

Biochemical and laboratory methods (by ELISA method)

2

Description

Interleukin-10

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods (by ELISA method)

3

Description

Interleukin-12

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods (by ELISA method)

4

Description

Fasting blood glucose

Timepoint

Before and after the protocol

Method of measurement

Biochemical methods

5

Description

Fasting blood insulin

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods (by ELISA method)

6

Description

Insulin resistance index (HOMA-IR)

Timepoint

Before and after the protocol

Method of measurement

formulas

Secondary outcomes

empty

Intervention groups

1

Description

Control group: This group received three 100 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 25 to 45 min training with 40% Maximum heart rate reserve, which in the final weeks reaches 80% of the Maximum heart rate reserve. Also, this group received three 100 mg starch tablets as a placebo during the 8-week intervention period).

Category

Treatment - Other

3

Description

Intervention group 2: Intervention group: Salvia officinalis supplement group (this group receives three tablets of 100 mg of So orally daily).

Category

Treatment - Other

4

Description

Intervention group 3: Training+ Salvia officinalis supplementation group (In this group the Simultaneous intervention, training, and Salvia officinalis supplementation, will treat with the same protocol describes in 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

Old Amol-Babol road, Kamdereh village- Ayatollah Amoli Branch, Islamic Azad University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Asieeh Abbassi Dalooi

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

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Alireza Barari

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Person responsible for updating data

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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.

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