

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The Protective Effect of Aerobic Training with *Salvia officinalis* Consumption on Endothelial Function Indices 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 the serum levels of Intercellular adhesion molecule (ICAM)-1, Soluble vascular cellular adhesion molecule 1 (sVCAM-1) and Endothelin-1 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. To place people in each group, Simple randomization by random allocation rule (balloting container and separate papers) is used.

Settings and conduct

The research site is Hejab Sports Club, Amol City. Since the exercise training did not have the ability to be blinded, the present study was performed in an unblinded manner. However, supplementation is blinded.

Participants/Inclusion and exclusion criteria

Being menopausal, Age range 50-65 years, inactive lifestyle, no drug use in the previous 6 months, and consent to participate in the study

Intervention groups

Control group: in this group we have not any intervention during 8 weeks, and will consider this group as placebo. Training group (This group performs 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 of *So* orally daily). Training+ *Salvia officinalis* supplementation group (In this group the Simultaneous intervention, training and *Salvia officinalis* supplementation, will treat with the same protocol that describe at the previous part).

Main outcome variables

Adhesion indexes such as: Intercellular adhesion molecule (ICAM-1), Soluble vascular cellular adhesion molecule 1 (sVCAM-1).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140415017288N10**

Registration date: **2023-02-14, 1401/11/25**

Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**

Update count: **0**

Registration date

2023-02-14, 1401/11/25

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

2023-04-04, 1402/01/15

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Protective Effect of Aerobic Training with Salvia officinalis Consumption on Endothelial Function Indices in Postmenopausal Women

Public title

Effect of Exercise and Salvia officinalis on Postmenopausal Women

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Being menopausal Age range 50-65 years Inactive lifestyle (exercise less than 1 hour per week) Do not use the drug in 6 months Satisfaction to participate in the study

Exclusion criteria:

Supplement use Diagnosis of other underlying 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

No information

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 Simple randomization by 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. The number 1 is for the Placebo Control group (C), the number 2 is for the Aerobic Training group (AT), the number 3 is for the Salvia officinalis group (So) and the 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)

Not blinded

Blinding description

Placebo

Used

Assignment

Factorial

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.1401.031

Health conditions studied

1

Description of health condition studied

Postmenopausal Women

ICD-10 code

N95.9

ICD-10 code description

Unspecified menopausal and perimenopausal disorder

Primary outcomes

1

Description

Intercellular adhesion molecule (ICAM)-1

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods (by ELISA method)

2

Description

Soluble vascular cellular adhesion molecule 1 (sVCAM-1)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods (by ELISA method)

Secondary outcomes

1

Description

Endothelin-1 (ET-1)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods (by ELISA method)

2**Description**

E-selectin

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods (by ELISA method)

3**Description**

Nitric Oxide (NO)

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods (by ELISA method)

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 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

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

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

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

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?**

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

Street address

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

City

Amol

Province

Mazandaran

Postal code

678

Phone

+98 11 4321 7124

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

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

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

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

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