

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The effect of of aerobic training plus Flax seed supplementation on serum lipids and lipoprotein profile and C-reactive protein in sedentary obese women.

#### Protocol summary

##### Summary

The objective of this study is to assess the effect of aerobic training with Flax seed supplementation on blood lipids profile and C-Reactive protein in sedentary obese women. Forty five obese/overweight women will participate in the study. The subjects will be randomly assigned to 3 groups (1- Aerobic training plus Flax seed supplementation. 2- Flax seed supplementation. 3- Control ). The group 1 will participate in a 10-week aerobic training [three times a week, 15-50 min/session and intensity of the exercise program is 50-75% heart rate max (HRmax)]. Blood lipids and C-Reactive protein (ELISA method) will be measured prior to and after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201309303387N4**

Registration date: **2013-10-28, 1392/08/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-10-28, 1392/08/06

##### Registrant information

###### Name

Abbas Saremi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 1277 7400

##### Email address

a-saremi@araku.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2013-05-31, 1392/03/10

##### Expected recruitment end date

2013-07-01, 1392/04/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of of aerobic training plus Flax seed supplementation on serum lipids and lipoprotein profile and C-reactive protein in sedentary obese women.

##### Public title

The effect of of aerobic training plus Flax seed supplementation on serum lipids and lipoprotein profile and C-reactive protein in sedentary obese women.

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: having a stable weight for at least 3 months prior to the study, age more than 30 years, body mass index more than 25, signing informed consent and presence of cardio-pulmonary. Exclusion criteria: Smoking.

##### Age

From **30 years** old to **55 years** old

##### Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 45

## Randomization (investigator's opinion)

Randomized

## 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

Arak University of Medical Sciences

##### Street address

Sardasht, University of Medical Sciences

##### City

Arak

##### Postal code

#### Approval date

2013-02-08, 1391/11/20

#### Ethics committee reference number

142-2-91

## Health conditions studied

### 1

#### Description of health condition studied

Obesity

#### ICD-10 code

E66.9

#### ICD-10 code description

Obesity, unspecified

## Primary outcomes

### 1

#### Description

Serum triglyceride

#### Timepoint

Baseline and after 10 weeks

#### Method of measurement

Glycerol phosphate oxidase, Enzymatic colorimetric

### 2

#### Description

Total cholesterol

#### Timepoint

Baseline and after 10 weeks

#### Method of measurement

Enzymatic photometric

### 3

#### Description

HDL-cholesterol

#### Timepoint

Baseline and after 10 weeks

#### Method of measurement

Enzymatic photometric

### 4

#### Description

LDL-cholesterol

#### Timepoint

Baseline and after 10 weeks

#### Method of measurement

Friedewald formula

### 5

#### Description

C-Reactive protein

#### Timepoint

Baseline and after 10 weeks

#### Method of measurement

ELISA assay

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Flax seed supplementation group: 9 grams/day powder of Flax seed.

#### Category

Treatment - Drugs

### 2

#### Description

Flax seed plus aerobic training group: 9 grams/day powder of Flax seed with aerobic training supervised by an exercise physiologist, 15-50 minute/day, 3day/week, for 10 weeks. The training program started at 50% of observed maximal heart rate (HRmax) and gradually increased to 75% of maximal heart rate by week 10. Aerobic training included treadmill walking/running.

#### Category

Treatment - Drugs

### 3

#### **Description**

The control group will maintain their lifestyle as usual.

#### **Category**

N/A

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Ghiasi Hospital

###### **Full name of responsible person**

Doctor Saremi Abbas

###### **Street address**

###### **City**

Arak

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Arak university

###### **Full name of responsible person**

Dr Shavandi

###### **Street address**

Pajohesh, Arak university, Shariati street, Arak

###### **City**

Arak

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Arak university

##### **Proportion provided by this source**

100

##### **Public or private sector**

*empty*

##### **Domestic or foreign origin**

*empty*

##### **Category of foreign source of funding**

*empty*

##### **Country of origin**

##### **Type of organization providing the funding**

*empty*

### **Person responsible for general inquiries**

##### **Contact**

###### **Name of organization / entity**

Arak University

###### **Full name of responsible person**

Dr Abbas Saremi

###### **Position**

Exercise physiologist

###### **Other areas of specialty/work**

##### **Street address**

Department of Physical Education and Sport Science,  
Arak University

##### **City**

Arak

##### **Postal code**

##### **Phone**

+98 86 1276 0104

##### **Fax**

##### **Email**

a-saremi@araku.ac.ir

##### **Web page address**

### **Person responsible for scientific inquiries**

##### **Contact**

###### **Name of organization / entity**

Arak University

###### **Full name of responsible person**

Dr Abbas Saremi

###### **Position**

Exercise physiologist

###### **Other areas of specialty/work**

###### **Street address**

Department of Physical Education and Sport Science,  
Arak University, Shariati street, Arak

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### **Person responsible for updating data**

##### **Contact**

###### **Name of organization / entity**

Arak University

###### **Full name of responsible person**

Dr Abbas Saremi

###### **Position**

Exercise physiologist

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*