Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of combined training with and without consuming the flaxseed ، on the estrogen hormone, also on the Lipid profile and insulin resistance of postmenopausal women

Protocol summary

Study aim
The purpose of this study would be studying the effect of the combined training on the estrogen hormone, the lipid profile and the insulin resistance, with and without using the flax seed, in the menopause women inactive.

Design
A clinical trial with a pre-test, post-test, community-based approach with two randomized groups

Settings and conduct
Location: City of Torbat Heydarieh Collecting samples from people referring to health centers. Semi-experimental research with two groups of combined exercises and combined exercise group with flaxseed

Participants/Inclusion and exclusion criteria
1.Inactive postmenopausal women 2.One year since the last menstruation 3.non-use of hormone therapy 4.having a BMI between 25 and 30 5.having a fat percentage of over 25 6.and having no regular exercise in the last 6 months

Intervention groups
Combined exercise group, Combined exercise group plus flaxseed supplement

Main outcome variables
Lipid Indices (LDL, HDL, TG, COL) Estrogen Insulin resistance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171031037142N2**
Registration date: **2018-02-12, 1396/11/23**
Registration timing: **retrospective**

Last update: **2018-02-12, 1396/11/23**
Update count: **0**

Registration date
2018-02-12, 1396/11/23

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 5229 9300
Email address
jahanshiri.nasrin@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-02-29, 1394/12/10

Expected recruitment end date
2016-04-08, 1395/01/20

Actual recruitment start date
2016-03-05, 1394/12/15

Actual recruitment end date
2016-04-08, 1395/01/20

Trial completion date
empty

Scientific title
The effect of combined training with and without consuming the flaxseed ، on the estrogen hormone, also on the Lipid profile and insulin resistance of postmenopausal women

Public title
The effect of combination training and flax on menopausal complications

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
One year since the last menstruation, having a body mass index of 25-30 kg / m2, having a fat percentage of over 25%,
Exclusion criteria:
not using hormone therapy and not having regular exercise in the last 6 months

Age
From **50 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **27**

Randomization (investigator's opinion)
Randomized

Randomization description
To determine the subjects in the training group and the exercise group with supplementation, from 1 to 30, it was written on small sheets and placed inside the box. Individuals extracted a number from the inside of the box before the first training session, if the desired number was paired, the person in the training group and, if the number was the one, the person was supplemented in the training group

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
Mashhad Ferdowsi University

Street address
Azadi Square, Ferdowsi University of Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۸۹۷۴

Approval date
2017-12-03, 1396/09/12

Ethics committee reference number
IR.MUM.FUM.REC.1396.05

Health conditions studied

1

Description of health condition studied
In this study, the disease has not been studied and the subjects are healthy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Estrogen is a collection of female sex hormones that consists of three main types of 17 beta-estradiol, estradiol and sterile, and is the main cause of female secondary sex traits. In this study, estradiol levels, the most important type of estrogen, were measured by blood sampling

Timepoint
Blood samples were collected for measuring estrogen 24 hours before and 48 hours after the last exercise session.

Method of measurement
To measure estrogen, the Japanese Toseh Kit was used

2

Description
Insulin resistance is called insulin resistance, because of the inability of the body to produce enough insulin or the inability to use insulin effectively. Insulin resistance was measured using the Homa formula.

Timepoint
Blood samples were collected for measuring insulin resistance 24 hours before and 48 hours after the last exercise session.

Method of measurement
In order to measure insulin and glucose, a kit of Pars tazmon was used in Iran

3

Description
Fat Profile: Blood lipids that appear in the form of triglycerides of cholesterol and lipoprotein (HDL, LDL).

Timepoint
Blood samples were collected for measuring fat profile, 24 hours before and 48 hours after the last exercise session.

Method of measurement
To determine the fat profile, the Pars azmon kits of Iran were used

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: combined training (The aerobic exercise was preformed with the intensity of 60 to 80 percent of the maximal heart rate and the resistance exercise with 4moves bench presses, wide grip last pull down, leg extension and lying leg curls with the intensity of 60 to 80 percent of a maximal repetition)

Category
Other

2

Description
Intervention group: combined training(The aerobic exercise was preformed with the intensity of 60 to 80 percent of the maximal heart rate and the resistance exercise with 4moves bench presses, wide grip last pull down, leg extension and lying leg curls with the intensity of 60 to 80 percent of a maximal repetition)plus flaxseed (using 25 grams of the milled flaxseed)

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Centers

Full name of responsible person
Heydarbeygi Mina

Street address
Valiasr Township, Daneshahr Crossroads

City
Torbat Heidariyeh

Province
Razavi Khorasan

Postal code
9516143440

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+98 51 5229 2584

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jahanshiri.nasrin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad Ferdowsi University

Full name of responsible person
Ahmad Reza Bahrami

Street address
Freedom Square, Ferdowsi University of Mashhad

City
Mashhad

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Razavi Khorasan

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pr@um.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad Ferdowsi University

Proportion provided by this source
75

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
Mashhad Ferdowsi University

Full name of responsible person
Jahanshiri Nasrin

Position
Physical Education Instructor

Latest degree
Master

Other areas of specialty/work
Physical Education / Exercise Physiology

Street address
Valiasr Township, Laleh 2, No. 12

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All individual data of the participants in this study can be subscribed to after being unidentifiable

When the data will become available and for how long

Start the access period 3 months after printing the results

To whom data/document is available

Researchers working in academic institutions and health centers

Under which criteria data/document could be used

Use data and research results to help the community and conduct further research

From where data/document is obtainable

Email jahanshiri.nasrin@yahoo.com

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

After receiving the email and ensuring that the reason for the request is one month

Comments

No specific explanation