

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Clinical trial of the effect of omega-3 fatty acids supplementation compared with the placebo on treatment and metabolic profiles in patients with endometrial hyperplasia

Protocol summary

Study aim

The aim of this study is to determine the effects of omega-3 fatty acids supplementation on treatment and metabolic profiles including insulin resistance and lipid profiles in patients with endometrial hyperplasia.

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 40 patients with endometrial hyperplasia of eligible and referred to Kosar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with endometrial hyperplasia and aged 35 to 55 years will be included in this study.
Exclusion criteria: Menopausal women, history of cardiovascular disease, hypertension, untreated thyroid disease, taking anti-inflammatory agents and Diabetes Mellitus.

Intervention groups

Intervention: Patients will be assigned to receive either omega-3 fatty acids (n=20) or placebo (n=20). Omega-3 fatty acids and placebo capsules are similar in shape and size.

Main outcome variables

Outcomes: Response to treatment and inflammatory markers (primary outcomes), and insulin metabolism parameters, lipid profiles and biomarkers of oxidative stress (secondary outcomes) will be quantified at the study baseline and end-of-trial.

General information

Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201701015623N98**

Registration date: **2017-01-10, 1395/10/21**

Registration timing: **retrospective**

Last update: **2019-10-31, 1398/08/09**

Update count: **1**

Registration date

2017-01-10, 1395/10/21

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2016-11-15, 1395/08/25

Expected recruitment end date

2016-12-15, 1395/09/25

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of omega-3 fatty acids supplementation compared with the placebo on treatment and metabolic profiles in patients with endometrial hyperplasia

Public title
Effect of supplementation in treatment of patients with endometrial hyperplasia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Aged 35-55 years old Patients with endometrial hyperplasia
Exclusion criteria:
 Menopausal women History of cardiovascular disease Hypertension Untreated thyroid disease Taking anti-inflammatory agents Diabetes Mellitus

Age
From **35 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak

City

Arak

Province

Markazi

Postal code

3814113634

Approval date

2016-11-14, 1395/08/24

Ethics committee reference number

IR.ARAKMU.REC.1395.310

Health conditions studied

1

Description of health condition studied

Endometrial hyperplasia

ICD-10 code

E11.2

ICD-10 code description

Endometrial hyperplasia

Primary outcomes

1

Description

Response to treatment

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Sonography

2

Description

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

2**Description**

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

3**Description**

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4**Description**

HDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

5**Description**

Total antioxidant

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

6**Description**

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

7**Description**

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

8**Description**

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

9**Description**

Fasting plasma glucose

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups**1****Description**

Inclusion criteria: Patients with endometrial hyperplasia; aged 30 to 50 years. Exclusion criteria: Unwillingness to cooperate.

Category

Treatment - Drugs

2**Description**

Control group: Placebo (Barij Essence, Kashan, Iran), twice a day, for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kosar Clinic

Full name of responsible person

Mehri Jamilian

Street address

Emam Khomeyni Avenue, Arak

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Arak

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Markazi

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Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafiee

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Arak University of Medical Sciences

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**

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available