Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Effects of combined omega-3 fatty acid and vitamin E supplementation compared with the placebo on metabolic profiles, inflammatory factors and biomarkers of oxidative stress in patients with breast cystic fibrosis

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of combined omega-3 fatty acid and vitamin E supplementation on metabolic profiles, inflammatory factor and biomarkers of oxidative stress in patients with breast cystic fibrosis.

Design

Study design: Parallel double-blind randomized controlled clinical trial.

Settings and conduct

Population and sample size: 56 breast cystic fibrosis eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with breast cystic fibrosis according to mammography criteria aged 30 to 55 years. Exclusion criteria: Pregnant women, patients with metabolic disorders including thyroid dysfunction, diabetes or impaired glucose tolerance.

Intervention groups

Intervention group: Omega-3 fatty acid and vitamin E capsule (Barij Essence Pharmaceutical Company, Kashan, Iran), 1000 mg omega-3 fatty acid and 400 mg vitamin E, daily for 12 weeks orally. Control group: Placebo capsule (Barij Essence Pharmaceutical Company, Kashan, Iran), daily for 12 weeks orally.

Main outcome variables

Outcomes: High-sensitivity C-reactive protein and nitric oxide (primary outcomes). Glucose homeostasis parameters, lipid profiles, biomarkers of oxidative stress (secondry outcomes).

General information

Reason for update

Due to an error, the request for an update in our website has been conducted after paper published. However, the revisions were in 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: **IRCT201510315623N55**
Registration date: **2015-11-20, 1394/08/29**
Registration timing: **retrospective**

Last update: **2019-11-09, 1398/08/18**
Update count: **1**

Registration date

2015-11-20, 1394/08/29

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2015-09-29, 1394/07/07

Expected recruitment end date

2015-10-30, 1394/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of combined omega-3 fatty acid and vitamin E supplementation compared with the placebo on metabolic profiles, inflammatory factors and biomarkers of oxidative stress in patients with breast cystic fibrosis

Public title

Effects of supplementation in the treatment of breast cystic fibrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with breast cystic fibrosis according to mammography criteria Aged 30 to 55 years

Exclusion criteria:

Pregnant women Patients with metabolic disorders including thyroid dysfunction, diabetes or impaired glucose tolerance

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and weeks of gestation, subjects will be randomly allocated into two treatment groups to take either supplements (n = 28) or placebo (n = 28). Randomization will be done by the use of Stat Trek software. Participants, investigators or the assessors of the outcomes are also unaware of the study groups.

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 at the Clinic who is not involved in the trial and not aware of random sequences will allocate the numbered bottles of capsules to participants. Supplements and placebo are in the same packaging at the pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

81151-87159

Approval date

2015-09-28, 1394/07/06

Ethics committee reference number

IR.Kaums.REC.1394.88

Health conditions studied

1

Description of health condition studied

Breast cystic fibrosis

ICD-10 code

N60.0

ICD-10 code description

Solitary cyst of breast

Primary outcomes

1

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

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
Fasting blood sugar
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
HDL-cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Total antioxidant
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
VLDL-cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

9

Description
LDL-cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation using HOMA formula

Intervention groups

1

Description
Intervention group: Omega-3 fatty acid and vitamin E capsule (Barij Essence Pharmaceutical Company, Kashan, Iran), 1000 mg omega-3 fatty acid and 400 mg vitamin E, daily for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule (Barij Essence Pharmaceutical Company, Kashan, Iran), daily for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Naghavi outpatient Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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+98 31 5554 0022
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research@kaums.ac.ir

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, Kashan 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
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Associate professor
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Nutrition
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Person responsible for updating data

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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