

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Omega 3 in the management of menopausal complication due to hormonal therapy in breast cancer patients

Protocol summary

Study aim

Omega 3 in the prevention of menopausal adverse event due to hormonal therapy in patients with breast cancer

Design

Randomized, double-blinded, placebo-control clinical trial

Settings and conduct

This study will be conducted in Seyedoshohada hospital, Isfahan. The enrolled patients will receive omega 3 or identical placebo 2 g daily for 4 weeks produced by by Zahravi company.

Participants/Inclusion and exclusion criteria

Adult women suffering from hormone-positive breast cancer with grade I to III who are receiving Selective estrogen receptor modulators (SERM) or Aromatase inhibitors (AIs) family drug and complaining of hot flash at least four times a week will be included. Those who are taking any drugs with the potential of central nervous system suppression such as anti-psychotic, antidepressant, anti-anxiolytic and anti-epileptic will be excluded.

Intervention groups

All patients who were considered as inclusion criteria, after signing the consent will be administrated randomly by whether omega 3 or identical placebo with 1 g twice a day for 4 weeks. Patients' information will be completed according to study's endpoints by data gathering sheet or standard and a valid questionnaire including Menopause Rating Scale (MRS), Daily menopause diary, Female Sexual Function Index (FSFI) at the baseline or 4 weeks after intervention.

Main outcome variables

hot flashes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040556N7**

Registration date: **2021-06-23, 1400/04/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-23, 1400/04/02**

Update count: **0**

Registration date

2021-06-23, 1400/04/02

Registrant information

Name

Azadeh Moghaddas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 7074

Email address

moghaddas@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Omega 3 in the management of menopausal complication due to hormonal therapy in breast cancer patients

Public title

Omega 3 in the management of breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult women suffering from hormone-positive breast cancer with grade I to III who are receiving Selective estrogen receptor modulators (SERM) or Aromatase inhibitors (AIs) family drug. Patients who are complaining from hot flash (at least 4 times in a previous month) Patients who have compliance and ability to take omega 3 orally

Exclusion criteria:

Patients who are in metastatic stage Patients who have a history of other malignancies except for breast cancer Patients who are receiving antipsychotic, anti-depression, anti-anxiolytic, sedative or hypnotic or anti-epileptic drugs Patients with a history of hypersensitivity reaction to omega 3

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The pockets containing medications (omega3 and placebo) will be coded, and each code will be written on the specific card. Thereafter, the eligible patient will be assigned to each group, randomly by selecting among shuffling cards. So, the allocation sequence will be concealed until the moment of assignment, and nobody knows what is the next treatment allocation. It should be mentioned that participants, health care providers, assessors, and data collector unaware of the assigned intervention (allocated codes).

Blinding (investigator's opinion)

Double blinded

Blinding description

For keeping participants, investigators, and health care providers will be kept blind, whole omega 3 tablets will be extracted from blister and separated into 60-tablets considered packages by the main investigator. Finally, all drugs and placebo packages will be labeled by codes extracted from internet-based software. After completion of recruitment, each patient's code was coordinated with software data, and the investigator or health care providers will be informed after data analyses of drugs' codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Faculty of Pharmacy, Isfahan University of medical Sciences, Hezar jarib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2020-09-23, 1399/07/02

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.390

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

The amount and severity of hot flash

Timepoint

Before intervention and 4 weeks

Method of measurement

Menopause Rating Scale (MRS) questionnaire

Secondary outcomes

1

Description

Sexual function

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

Female Sexual Function Index questionnaire

Intervention groups

1

Description

Intervention group: Omega 3 capsules 2 g daily (twice a day orally) for 4 weeks provided by Zahravi pharmaceutical Company, and then baseline and 4-weeks follow-up demographic data and questionnaire according to studies endpoints.

Category

Treatment - Drugs

2

Description

Control group: Identical placebo capsule similar to omega 3 capsule which has been provided by Zahravi pharmaceutical Company twice a day orally for 4 weeks and then baseline and 4-weeks follow-up demographic data and questionnaire according to studies endpoints.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed al-Shohada Teaching Hospital

Full name of responsible person

Azadeh Moghaddas

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Faculty of Pharmacy, Isfahan University of Medical Sciences, Hezar Jarib, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjou

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan, Iran

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Grant name

Vice-Chancellery for Research of Isfahan University of Medical Sciences

Grant code / Reference number

50270

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Azadeh Moghaddas

Position

Assistant Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected data

When the data will become available and for how long

From the summer of 2022

To whom data/document is available

All academic centres

Under which criteria data/document could be used

All documents with citation

From where data/document is obtainable

From the main investigator, Azadeh Moghaddas via azadeh_moghaddas@yahoo.com address E-mail

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

After sending a request, we will call the related person and the data will be revealed in less than one week

Comments