Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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+98 31 1792 7074

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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
Isfehan
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
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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
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Other areas of specialty/work
Others
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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