

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Omega 3 in the management of mood and sleep changes complication due to hormonal therapy in breast cancer patients:

#### Protocol summary

##### Study aim

1) Determination and comparison of the mean number of hot flash during a day between intervention and placebo group 2) Determination and comparison of the severity of hot flash during a day between intervention and placebo group 3) Determination and comparison of the Menopause Rating Scale (MRS) criteria during a day between intervention and placebo group 4) Determination and comparison of the Sexual functional criteria during a day between intervention and placebo group 5) Determination and comparison of the Pittsburgh Sleep Quality Index (PSQI) during a day between intervention and placebo group.

##### Design

Two arms randomised blind trial.

##### Settings and conduct

This study will be conducted in Seyedoshohada hospital. The enrolled patients will receive omega3 or identical placebo with dose of 2gr daily for 4 weeks prepared by Razak 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 omega3 or identical placebo with 1gr 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), The Pittsburgh

Sleep Quality Index 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: **IRCT20180722040556N6**

Registration date: **2021-03-01, 1399/12/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-03-01, 1399/12/11**

Update count: **0**

##### Registration date

2021-03-01, 1399/12/11

##### 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

2020-05-18, 1399/02/29

##### Expected recruitment end date

2022-03-19, 1400/12/28

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Omega 3 in the management of mood and sleep changes 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 omega3 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**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done by Blocked randomization method. Information such as the number of intervention groups (two main intervention groups, for example, A and control, for example, B), block size (multiple numbers of groups, in this study to reduce complexity, 4 will be selected). The total number of patients (sample size 60) will be entered into Internet-specific software for this calculation (for example, available at " the Create a blocked randomisation list | Sealed Envelope"). For each included patients, a specific code will be allocated in order to determine the type of included group. The predicted sample size of patients will be accomplished randomly by using this method. The main investigator will allocate the concealed code to control group or case group according to random numbers and will put them to investigators who are in charge of sampling.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

For keeping participants, investigator and health care providers blind, whole omega 3 tablets will be extracted from blister and separated in 60-tablets considered packages by the main investigator. Finally, all drugs and placebo packages will be labelled by codes extracted from internet-based software. After completion of recruitment, each patients code were coordinated with software data and 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**

2020-09-22, 1399/07/01

**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: Intervention group: Administration of 1 g capsule of omega 3 provided by Zahravi pharmaceutical Company, 2 g daily (twice a day orally) for 4 weeks and then baseline and 4-weeks follow-up demographic data and questionnaire according to studies endpoints.

### Category

Treatment - Drugs

2

### Description

Intervention group: Control group: Administration of identical placebo capsule similar to omega 3 capsule which have 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

#### Street address

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

#### City

isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3792 7074

#### Email

azadeh\_moghaddas@yahoo.com

## 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

#### City

isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3792 7074

#### Email

azadeh\_moghaddas@yahoo.com

### 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?

No

### 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

Other

## 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

other

#### Street address

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

#### City

isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 7074

**Email**

azadeh\_moghaddas@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Azadeh Moghaddas

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

other

**Street address**

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

**City**

isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 7074

**Email**

azadeh\_moghaddas@yahoo.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Azadeh Moghaddas

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

other

**Street address**

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

**City**

isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 7074

**Email**

azadeh\_moghaddas@yahoo.com

**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 2021

**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**

E-mail address

**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**