

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Comparison of the Effect of Omega3 and Folic Acid Oral Tablet on Hot Flashes in Menopausal Women

#### Protocol summary

##### Summary

**Objective:** The Comparison of the Effect of Omega3 and Folic Acid Oral Tablet on Hot Flashes in Menopausal Women(2) **Study design:** The sampling will be random and triple blind. This study will be placebo-controlled and single center. The study population : Iranian origin of all menopausal women with hot flashes,Sample size: 120 (3): In this semi-experimental study will participate 120 menopausal women with hot flashes (4): **Inclusion criteria :** Iranian, age 45-60 years, menopause is the normal type have,reporting at least two times hot flashes per day , with literacy being studied components or a family member, body mass index 20 to 30, non receiving hormone therapy , anti-depressants or tranquilizers, supplements and herbal medicines, no known underlying disease (hypertension, diabetes, epilepsy, etc.), the lack of experience of such as relatives died in the last 6 months of stress, separation of spouses and absence of estrogen-dependent cancer, non consumption of more than 2 servings of fish per weeks, insensitivity to fish or fish oil, seafood, avoiding the use of any drugs to improve the symptoms of hot flashes, at least one year and a maximum of three years have menstruation, exercise not more than 2 times a week for 20-30Dqyqh,Exclusion criteria: the other drug use during the study, in case of complications or allergic drugs (omega-3 or folic acid), identifying any physical or mental illness during the study, lack of proper use of drugs or placebo over three days (5) **Intervention:** They are divided into three groups. Group 1: omega3 1 tablet 1000 mg daily, group 2: folic acid 1 tablet 1 mg daily, group 3: placebo 1tablet daily, for three months (6) **Primary outcome measure:**Intensity, duration and frequency of hot flashes

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017011131880N1**

Registration date: **2017-01-24, 1395/11/05**

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

Last update:

Update count: **0**

##### Registration date

2017-01-24, 1395/11/05

##### Registrant information

###### Name

masoumeh chamani

###### Name of organization / entity

دانشگاه علوم پزشکی ایران

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8670 5503

###### Email address

chamani.m@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Iran University of Medical Sciences

##### Expected recruitment start date

2016-11-21, 1395/09/01

##### Expected recruitment end date

2017-04-21, 1396/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Comparison of the Effect of Omega3 and Folic Acid Oral Tablet on Hot Flashes in Menopausal Women

**Public title**

The Comparison of the Effect of Omega3 and Folic Acid Oral Tablet on Hot Flashes in Menopausal Women

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria : Iranian, age 45-60 years, menopause is the normal type have, reporting at least two times hot flashes per day , with literacy being studied components or a family member, body mass index 20 to 30, non receiving hormone therapy , anti-depressants or tranquilizers, supplements and herbal medicines, no known underlying disease (hypertension, diabetes, epilepsy, etc.), the lack of experience of such as relatives died in the last 6 months of stress, separation of spouses and absence of estrogen-dependent cancer, non consumption of more than 2 servings of fish per weeks, insensitivity to fish or fish oil, seafood, avoiding the use of any drugs to improve the symptoms of hot flashes, at least one year and a maximum of three years have menstruation, exercise not more than 2 times a week for 20-30Dqyqh, Exclusion criteria: the other drug use during the study, in case of complications or allergic drugs (omega-3 or folic acid), identifying any physical or mental illness during the study, lack of proper use of drugs or placebo over three days

**Age**

From **45 years** old to **60 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Randomization: Sample allocation in the case and control group will be conducted randomly and using lottery through numbering 1, 2 and 3 on the cards. The samples will be asked to pick a card. By choosing a card, randomly the sample will be placed in one of the following groups: Group Evening omega3 (1 tablet 1000 mg daily), folic acid (1 tablet 1 mg daily) and placebo groups (1 capsules daily) Blinding: the medicine (omega3 and folic acid) and placebo in the form of similar tablet will be produced by pharmacology advisor. Also putting capsules in the same containers and coding them will be performed by him. And at the end of the study and after analyzing the results, the tablet containers will be decoded. Thus, the samples are not aware of the contents of the medicine containers. As well as

researchers and statistical analysts are not aware of the contents of the medicine containers and each groups What medications are taking. So, the study is a triple-blind

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Iran University of Medical Sciences

**Street address**

School of Nursing and Midwifery, Yasemi Rashid Street, Valiasr Street, Tehran

**City**

tehran

**Postal code**

1996713883

**Approval date**

2016-08-08, 1395/05/18

**Ethics committee reference number**

IR. IUMS. REC 1395 - 9311373012

**Health conditions studied****1****Description of health condition studied**

menopause

**ICD-10 code**

N95.1

**ICD-10 code description**

Menopausal and female climacteric states

**Primary outcomes****1****Description**

The severity of hot flashes

**Timepoint**

Before the intervention, one month and two months and three months after intervention

**Method of measurement**

Daily hot flash diary form

**Secondary outcomes****1****Description**

duration of hot flashes

**Timepoint**

Before the intervention, one month and two months and three months after intervention

**Method of measurement**

Daily hot flash diary form

## 2

### Description

Frequency hot flashes

### Timepoint

Before the intervention, one month and two months and three months after intervention

### Method of measurement

Daily hot flash diary form

## Intervention groups

### 1

#### Description

Intervention group:omega3 1 tablet 1000 mg daily, group folic acid 1 tablet 1 mg daily.omega3 is made zahravi , folic acid made Shahid Beheshti University of Medical Science in the School of Pharmacy

#### Category

Placebo

### 2

#### Description

Control group: placebo 1 tablet daily for 3 months , made School of Pharmacy Shahid, Beheshti University of Medical Sciences

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

north west public health centers affiliated Iran University of Medical Sciences

##### Full name of responsible person

Zahra Keshavarzian

##### Street address

60/5000 Ministers street, opposite the cinema release, North West of Tehran Health Center

##### City

tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

##### Full name of responsible person

Morteza Naser Bakhat

##### Street address

Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran

#### City

tehran

#### 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, Iran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences, School of Nursing and Midwifery

##### Full name of responsible person

masoumeh chamani

##### Position

Master student of midwifery

##### Other areas of specialty/work

##### Street address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

University of Medical Sciences Iran, School of Nursing and Midwifery

##### Full name of responsible person

Fereshteh Jahdi

##### Position

Master of Midwifery

##### Other areas of specialty/work

##### Street address

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

University of Medical Sciences Iran, School of Nursing and Midwifery

**Full name of responsible person**

masoumeh chamani

**Position**

Master Student Of Midwifery

**Other areas of specialty/work**

**Street address**

Rastvan Street, Pasdaran Street, Tehran

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*