

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The effect of Soybean and Fish oil tablets on control of hot flash, sexual and sleep disorders in pre-menopausal and menopausal women 45-64 years old

#### Protocol summary

##### Study aim

Comparison of the effect and comparative study of the effect of soy and fish oil tablets in control of hot flash and night sweats in terms of frequency and severity of symptoms of sexual disorders and sleep disorders in 45-64 year old menopausal and pre-menopausal women

##### Design

A randomized controlled clinical trial with double blinded parallel groups

##### Settings and conduct

The sampling method in this study was random sampling among patients referred to Rasoul Akram Clinics and 159 patients were selected randomly based on inclusion and exclusion criteria. The drugs were placed in two envelopes that the researcher did not know about the contents. In the three groups, hot flash were compared in terms of frequency and severity.

##### Participants/Inclusion and exclusion criteria

The study population consisted of 159 women referred to Hazrat Rasoul Hospital who were evaluated according to inclusion and exclusion criteria. Inclusion criteria: Ages between 45 and 64 years Not allergic to soy and fish liver pills Having informed consent for inclusion. Exclusion criteria: Lack of reading and writing skills and unable to answer questions No phone calls to follow up Having a history of more than 10 years of menopause Contraindications to hormone therapy include suspected or diagnosed cancer.

##### Intervention groups

The intervention in the groups consisted of soybean oil, fish liver oil and no drug group. The soybean group received one soybean pills containing 500mg of pure soybean extract daily, and the fish oil group received one fish liver oil pills daily containing 1000mg of fish oil and 180 mg eicosapentaenoic acid and 120mg of docosahexaenoic acid for three months. The third group did not receive drugs.

##### Main outcome variables

In the three study groups, night sweats, hot flash frequency and severity of expression, sexual dysfunction and sleep disorders as well as possible side effects determined were compared.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200222046584N1**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **retrospective**

Last update: **2020-03-19, 1398/12/29**

Update count: **0**

##### Registration date

2020-03-19, 1398/12/29

##### Registrant information

##### Name

Bahareh Purzand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6435 2658

##### Email address

bahareh.purzand@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-02, 1397/07/10

##### Expected recruitment end date

2019-10-02, 1398/07/10

**Actual recruitment start date**

2018-10-02, 1397/07/10

**Actual recruitment end date**

2019-10-02, 1398/07/10

**Trial completion date**

2019-10-02, 1398/07/10

**Scientific title**

The effect of Soybean and Fish oil tablets on control of hot flash, sexual and sleep disorders in pre-menopausal and menopausal women 45-64 years old

**Public title**

Effect of soybean and fish liver oil on control of hot flashes, sexual disorders and sleep disorders

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Ages between 45 and 64 years Not allergic to soy and fish liver pills Having informed consent for inclusion

**Exclusion criteria:**

Lack of reading and writing skills and unable to answer questions No phone calls to follow up Having a history of more than 10 years of menopause Concomitant use of sulfanamides, methotrexate, triamethrenone, sulfasalazine, estrogen, phenytoin, anti-anxiety and antidepressants, daily chemicals and multivitamins, aspirin and painkillers Hormone therapy and OCP use over the past 3 months Use of complementary herbs to remove vasomotor symptoms over the past month Contraindications to hormone therapy include suspected or diagnosed cancer

**Age**

From **45 years** old to **64 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **159**

Actual sample size reached: **159**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sampling method in this study is simple random sampling. Patients were randomly divided into three groups(Decussate)

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The drugs were placed in two envelopes that the researcher did not know about the contents of the envelopes and had A and B written on them.The intervention in the groups consisted of soybean oil, fish liver oil . In the three groups, hot flash and night sweats were compared in terms of frequency and severity, sex

and sleep disorders, as well as potential adverse effects.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Iran University of Medical Sciences

**Street address**

Vice Chancellor for International affairs, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran,

**City**

Tehran

**Province**

Tehran

**Postal code**

14665-354

**Approval date**

2019-10-23, 1398/08/01

**Ethics committee reference number**

IR.IUMS.FMD.REC.1397.9511290004

**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**

Comparison of the effect of soy tablets and fish liver oil on TSH level

**Timepoint**

Before and after the intervention

**Method of measurement**

TSH measurement in blood

**2****Description**

Comparison of the effect of soy and liver oil pill on lipid profile

### **Timepoint**

Before and after the intervention

### **Method of measurement**

lipid profile measurement in blood

### **3**

#### **Description**

Measuring the number of hot flashes

#### **Timepoint**

Before and after the intervention

#### **Method of measurement**

Patient MRS questionnaire

### **4**

#### **Description**

Measuring the number of times a patient wakes up

#### **Timepoint**

Before and after the intervention

#### **Method of measurement**

Patient MRS questionnaire

### **5**

#### **Description**

Patient's sexual reluctance

#### **Timepoint**

Before and after the intervention

#### **Method of measurement**

Patient MRS questionnaire

### **6**

#### **Description**

Vaginal dryness

#### **Timepoint**

Before and after the intervention

#### **Method of measurement**

Patient MRS questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group one: Patients receive soy pills.

#### **Category**

Prevention

### **2**

#### **Description**

Intervention group: Patients receive fish liver oil pills.

#### **Category**

Prevention

### **3**

#### **Description**

Control group: They don't receive any drugs.

#### **Category**

Prevention

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Rasoul Akram Hospital

##### **Full name of responsible person**

Bahareh Purzand

##### **Street address**

Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan Av, Tehran, Iran

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1449614535

##### **Phone**

+98 21 6435 2434

##### **Email**

bahareh.purzand@yahoo.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Abbas Motevalliyan

##### **Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

##### **City**

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##### **Phone**

+98 21 8670 2503

##### **Email**

research-m@iums.ac.ir

##### **Web page address**

<https://vcr.iums.ac.ir/>

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Bahareh Pourzand

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Bahareh Purzand

**Position**

Resident of Obstetrics and Gynecology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Bahareh Purzand

**Position**

Resident of Obstetrics and Gynecology

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Email**

bahareh.purzand@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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Age control night sweats, hot flash, the frequency of occurrence, sexual dysfunction and sleep disorders listed in the questionnaire.

**When the data will become available and for how long**

Since 2022 and after being published in magazines

**To whom data/document is available**

Researchers and people working in the pharmaceutical industry

**Under which criteria data/document could be used**

Providing evidence for continuing studies in this field or manufacturing as industrial drugs

**From where data/document is obtainable**

Dr. Bahar Pourzand via Email:  
bahareh.purzand@yahoo.com

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

discuss their demands and explain the reasons for it via Email

**Comments**