

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 Rasoule Akram Hospital, Niayesh St, Satarkhan Av, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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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Person responsible for updating data

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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

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