Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 didnot 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 dont 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Abbas Motevalliyan
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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran,Iran
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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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Resident of Obstetrics and Gynecology

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Medical doctor

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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