Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of the treatment effects of soy, trigonellafoenum, and combined them under the control of vasomotor symptoms among postmenopausal women

Protocol summary

Summary

The aim of the study was to determine the prevalence of vasomotor symptoms and the effect of soy nuts, soy and fenugreek seeds on reducing symptoms in 60 postmenopausal women who Chamran was referred to a hospital clinic. Inclusion criteria: postmenopausal symptoms and tests LH, FSH, estradiol, and a natural process without the involvement of medical and surgical menopause - amenorrhea for more than 6 months and a maximum of ten years of menopause Non-inclusion criteria: cardiovascular drugs, blood clotting disorders, thyroid disorders, hormonal, allergic to soy and tobacco sub cycle education Exclusion criteria: susceptibility to various diseases during the study. Patients were divided into three groups on the basis of allocation can be divided into a control group. The experimental groups, soybean, soybean and fenugreek fenugreek'm taking the placebo group (toasted flour) 30 g reat 6,100,60 and the use of supplements Nmvdnd.dr the serum levels of LH, FSH and estradiol vasomotor symptoms patients were measured before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090912628N1**
Registration date: **2014-11-12, 1393/08/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-12, 1393/08/21

Registrant information

Name

Mohammad Samadi

Name of organization / entity

Baqiyatallah University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 2407

Email address

m.samadi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Faculty of Health, Health and Nutrition Research Center

Expected recruitment start date

2014-03-06, 1392/12/15

Expected recruitment end date

2014-09-03, 1393/06/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the treatment effects of soy, trigonellafoenum, and combined them under the control of vasomotor symptoms among postmenopausal women

Public title

Effect of soy, trigonellafoenum, and combined them under the control of common vasomotor symptoms

Purpose

Supportive

Inclusion/Exclusion criteria

Menopause symptoms experiments, LH, FSH and estradiol, a natural process of menopause menstruation surgery without medical intervention over 6 months and

a maximum of ten years of menopause, the withdrawal from the study: cardiovascular drugs, blood clotting disorders, thyroid disorders, hormonal, smoking is allergic to soy and education under secondary

Age
From **44 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Baqiyatallah University of Medical Sciences

Street address
Sheikh bahaei, Molla sadra, Vanak

City
Tehran

Postal code
8475421591

Approval date
2013-11-11, 1392/08/20

Ethics committee reference number
340.3.6434

Health conditions studied

1

Description of health condition studied
Vasomotor symptoms

ICD-10 code
R00-R99

ICD-10 code description
R50-R69

Primary outcomes

1

Description
FSH LH E2

Timepoint
pre intervention - post intervention

Method of measurement
miclu/l , miclu/l pg/m

Secondary outcomes

1

Description
Signs and Symptoms of Menopause

Timepoint
pre intervention -- post intervention

Method of measurement
MRS questionnaire

Intervention groups

1

Description
Group I: 60 kg soy nut daily

Category
Placebo

2

Description
Group II: only 6 grams daily TF

Category
Treatment - Drugs

3

Description
Group III: 60 grams of soy plus 6 grams of fenugreek daily

Category
Treatment - Drugs

4

Description
Group IV: 30 grams flour toasted Daily

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Chamran Hospital

Full name of responsible person
Monirsaadat Mahdavi

Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Rahim Sorory
Street address
Baqiyatallah University of Medical Science, South sheikh-Bahaei street, Mollasadra Avenue, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Baqiyatallah 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
Faculty of Health Baqiyatallah University of Medical Sciences
Full name of responsible person
Mohammad Samadi
Position
PHD nutrition
Other areas of specialty/work
Street address
Baqiyatallah University of Medical Science, South sheikh-Bahaei street, Mollasadra Avenue, Tehran, Iran
City
Tehran
Postal code
8945641259
Phone
+98 21 8248 3131
Fax
Email
m.samadi@bmsu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Baqiyatallh University of Medical Sciences
Full name of responsible person
Monir Sadat Mahdavi
Position
M.Sc candidate
Other areas of specialty/work
Street address
Baqiyatallah University of Medical Science, South sheikh-Bahaei street, Mollasadra Avenue, Tehran, Iran
City
Tehran
Postal code
7845965412
Phone
+98 21 2795 2431
Fax
Email
ms.mahdavi@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samadi
Position
Ph. D
Other areas of specialty/work
Street address
Sheikh Bahaee St
City
Tehran
Postal code
78451254841
Phone
+98 21 8804 0153
Fax
Email
samadi.mohammad@yahoo.com, samadi@bmsu.ac.ir
Web page address

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*