Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Effect of soybean supplementation and regular aerobic exercise in water on mental and physical symptoms of premenstrual syndrome (PMS) female students

Protocol summary

Summary

The purpose of this study is to evaluate the effect of soybean supplementation and regular aerobic exercise in water on mental and physical symptoms of premenstrual syndrome (PMS) in a randomized double-blinded clinical trial design. 92 single patients with PMS are students of Shahrood University of Technology and according to inclusion criteria such as patient between the ages 18-24 year old with normal menstrual cycle and exclusion criteria such as athlete patients with use of OCP (Combined oral contraceptives) or non-compliance with treatment and after being inform about the aim of present investigation and signed an informed consent form will randomly assign into four intervention groups, patients with PMS (23 girls) and regular aquatic exercise (doing water walking and crawl in the water with 50-60% heart rate for 30 minutes and doing water-polo for 20 minutes) during 8 weeks, patients with PMS and use of soybean supplementation (23 girls) that ingest 60 soybean supplementation capsules (one capsule each day after lunch) during 8 weeks, patients with PMS and regular aquatic exercise and use of soybean supplementation (23 girls) same as other intervention groups and control group: patients with PMS (23 girls) and use placebo (one capsule filled with Elaeagnus angustifolia powder which will administered by a blinded research assistant for each day after lunch during 8 weeks).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011221412N2**
Registration date: **2016-05-21, 1395/03/01**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-05-21, 1395/03/01

Registrant information

Name
Hamid Kalalian Moghadam
Name of organization / entity
Shahroud University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-06-19, 1393/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of soybean supplementation and regular aerobic exercise in water on mental and physical symptoms of premenstrual syndrome (PMS) female students

Public title

Effect of soybean supplementation and regular aerobic

exercise in water on mental and physical symptoms of premenstrual syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: female gender between the ages 18-24 year old; Single; normal cycle (duration of cycle 21-35, bleeding 3-10 days); normal BMI with PMS. Exclusion criteria: any history of disease such as hepatic; renal or respiratory cardiac; diabetes; or respiratory diseases, presence of secondary dysmenorrheal; sea food allergy; use of alcohol, smoking; presence of chronic diseases such as like migraine; use of any drug affecting PMS such as OCP or B6; stressful condition like death of family members.

Age
From **18 years** old to **24 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
For elimination of the possibility of any probable bias due to the knowledge of patients and assessing physicians about the type of treatment we will perform a double blind study. Soybean supplementation and Elaeagnus angustifolia powder as placebo will be encapsulated and for this reason patients and assessing physicians do not have any knowledge about the type of treatment. Randomization will be performed by the Randlist software and every patient will be entered into four intervention groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences

Street address
Shahroud University of Medical Sciences, Haftom Tir Square

City
Shahroud

Postal code

Approval date
2014-06-11, 1393/03/21

Ethics committee reference number
930/06

Health conditions studied

1

Description of health condition studied
Premenstrual Syndrome (PMS)

ICD-10 code
N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
body fat percentage

Timepoint
8 weeks after intervention

Method of measurement
Body analyzer

2

Description
waist-to-hip ratio (WHR)

Timepoint
8 weeks after intervention

Method of measurement
Body analyzer

3

Description
premenstrual syndrome (existing symptoms in PSST questionnaire)

Timepoint
8 weeks after intervention

Method of measurement
Body analyzer

4

Description
Body water

Timepoint
8 weeks after intervention

Method of measurement
Body analyzer

5

Description
Fat-free mass index

Timepoint
8 weeks after intervention
Method of measurement
Body analyzer

6

Description
Body Mass Index
Timepoint
8 weeks after intervention
Method of measurement
Body analyzer

7

Description
skeletal muscle mass
Timepoint
8 weeks after intervention
Method of measurement
Body analyzer

8

Description
Body Fat Mass
Timepoint
8 weeks after intervention
Method of measurement
Body analyzer

9

Description
Weight
Timepoint
8 weeks after intervention
Method of measurement
Body analyzer

10

Description
Basal Metabolic Rate (BMR)
Timepoint
8 weeks after intervention
Method of measurement
Body analyzer

11

Description
body impedance analysis
Timepoint
8 weeks after intervention
Method of measurement
Body analyzer

Secondary outcomes

empty

Intervention groups

1

Description
Contrtol group: patients with PMS (23 girls) which use placebo (one capsule filled with senjed powder for each day after lunch during 8 weeks)
Category
Placebo

2

Description
Intervention group: single patients with PMS during 8 weeks will use of one capsule of soybean supplementation each day
Category
Treatment - Drugs

3

Description
Intervention group: single patients (23 girls) with PMS and regular aquatic exercise during 8 weeks with 50-60% heart rate for 30 minutes
Category
Other

4

Description
Intervention group: patients with PMS (23 girls) and regular aquatic exercise with 50-60% heart rate for 30 minutes will use of one capsule of soybean supplementation each day during 8 weeks
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Hamid Kalalian Moghadam
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Shahroud University of Medical Sciences, Haftom Tir Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahroud University of Medical Sciences

Full name of responsible person
Dr. Hamid Kalalian Moghadam
Street address
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City
Shahroud
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, Shahroud 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
Shahroud University of Medical Sciences
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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