

# 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

Shahrood University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3239 5054

###### Email address

h.kalalian@shmu.ac.ir

##### 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 dysmenorrhea; 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**

Control 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**

Shahrood University of Medical Sciences

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

Dr. Hamid Kalalian Moghadam

##### **Street address**

Shahrood University of Medical Sciences, Haftom Tir Square

##### **City**

Shahrood

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Vice chancellor for research, Shahrood University of Medical Sciences

**Full name of responsible person**

Dr. Hamid Kalalian Moghadam

**Street address**

Shahroud University of Medical Sciences, Haftom Tir Square

**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

**Full name of responsible person**

Dr. Hamid Kalalian Moghadam

**Position**

Assistant Professor of Physiology, Shahroud University of Medical Sciences

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**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*