

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparison the effects of 2 month of regular Aerobic exercise and vitamin B6 intake on the Symptoms of premenstrual syndrome in Non-Athlete student girls

#### Protocol summary

##### Summary

The main objective of this project is to Comparison the effects exercise of aerobic and vitamin B6 intake on the symptoms of premenstrual-syndrome in Non-athlete girls. 60 girl university students in Khorasgan University with inclusion and exclusion criteria: aged between 18-25 years old; single; healthy; with regular menstrual periods and Non-Athlete were chosen by the use of complementary questionnaires including dairy symptoms recording table, (DMS-IV) Premenstrual syndrome, General Health (GHQ28), Beck depression and anxiety questionnaire and were divided in three Aerobic exercise and vitamin B6 and control groups randomly. The activities lasted for 2 months, 3 sessions in a week, and each session 60 minutes. The experimental group vitamins B6 were used a pill every day for 2 months. After 1 months the PMS questionnaire was distributed among the 3 groups again (mid-test) and after 2 months the posttest was conducted. The results show that physical and psychological symptoms reduced after 1 and 2 months exercise and vitamin B6 intake. Also the results indicate that the mean score in decreasing physical, psychological symptoms and total score in Aerobic was more than vitamins B6 and control group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013082614428N2**

Registration date: **2013-10-27, 1392/08/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-10-27, 1392/08/05

#### Registrant information

##### Name

Zeinab Samadi

##### Name of organization / entity

Islamic Azad University, Khorasgan (Isfahan) Branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1231 3100

##### Email address

samadi1404@yahoo.com

#### Recruitment status

##### Recruitment complete

#### Funding source

Islamic Azad University, Khorasgan

#### Expected recruitment start date

2011-06-26, 1390/04/05

#### Expected recruitment end date

2013-04-21, 1392/02/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison the effects of 2 month of regular Aerobic exercise and vitamin B6 intake on the Symptoms of premenstrual syndrome in Non-Athlete student girls

#### Public title

Comparison the effects of 2 month of regular Aerobic exercise and vitamin B6 intake on the Symptoms of premenstrual syndrome

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: aged between 18-25 years old; single; with regular menstrual periods; bleeding between menstrual cycle length of 22-35 days ,for 3-8 days.  
Exclusion criteria : history of regular physical activity for 3 months before starting the study and during the study;history of diseases such as asthma, diabetes, renal, cardiac, psychiatric, thyroid, epilepsy;medication or being on a special diet.

**Age**

From **18 years** old to **25 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **25**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Isfahan

**City**

Isfahan

**Postal code****Approval date**

2011-06-26, 1390/04/05

**Ethics committee reference number**

290064

**Health conditions studied****1****Description of health condition studied**

Premenstrual Syndrome

**ICD-10 code**

N94.3

**ICD-10 code description**

Premenstrual tension syndrome

**Primary outcomes****1****Description**

Physical symptoms premenstrual syndrome

**Timepoint**

After, 1 months the PMS and after 2 months the posttest

**Method of measurement**

Questionnaires including dairy symptoms recording table, (DMS-IV) PMS, General Health (GHQ28), Beck depression and anxiety questionnaire

**2****Description**

Psychological symptoms premenstrual syndrome

**Timepoint**

After, 1 months and after 2 months the posttest

**Method of measurement**

Questionnaires including dairy symptoms recording table, (DMS-IV) PMS, General Health (GHQ28), Beck depression and anxiety questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The experimental group vitamins B6 were used a pill every day for 2 months.

**Category**

Treatment - Drugs

**2****Description**

The activities lasted for 8 weeks, 3 sessions in a week, and each session 60 minutes.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

, IslamiIslamic Azad University, Khorasgan (Isfahan)

Branch

**Full name of responsible person****Street address****City**

Isfahan

**Sponsors / Funding sources**

## 1

### **Sponsor**

**Name of organization / entity**

School of Nursing and Midwifery, Isfahan University of Medical Sciences

**Full name of responsible person**

Muosavi

**Street address**

Isfahan University of Medical Sciences

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

School of Nursing and Midwifery, Isfahan 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**

Islamic Azad University, Khorasgan (Isfahan) Branch

**Full name of responsible person**

zeinab samadi

**Position**

MSC

**Other areas of specialty/work**

**Street address**

Islamic Azad University, Khorasgan (Isfahan) Branch

**City**

Isfahan

**Postal code**

**Phone**

+98 913 268 7830

**Fax**

**Email**

samadi1404@yahoo.com

**Web page address**

### **Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University, Khorasgan (Isfahan) Branch

**Full name of responsible person**

zeinab samadi

**Position**

MSC

**Other areas of specialty/work**

**Street address**

Arghavanieh street, Jey street.

**City**

Isfahan

**Postal code**

**Phone**

+98 913 268 7830

**Fax**

**Email**

samadi1404@yahoo.com

**Web page address**

### **Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University, Khorasgan (Isfahan) Branch

**Full name of responsible person**

zeinab samadi

**Position**

MSc

**Other areas of specialty/work**

**Street address**

Arghavanieh street, Jey street.

**City**

Isfahan

**Postal code**

**Phone**

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**Fax**

**Email**

Samadi1404@yahoo.com

**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*