

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of dried black seed grape (vitis vinifera) on clinical and mood symptom in Students with premenstrual syndrome

#### Protocol summary

jafarirad-s@ajums.ac.ir

#### Summary

this study was designed to investigate the effect of Dried black seed grape on clinical and mood symptom in Students with premenstrual syndrome. sample size is 200 that will be divided into two groups (Dried black seed grape group and control). the period of intervention is Two seven-day period that symptom will be assay in any period end by questionnaire. inclusion criteria is the risk of moderate and severe forms with age 18-35 years and exclusion criteria is Failure to use 80% dried black seed grape during the intervention. The primary outcomes are Effect of physical and mood and psychical symptom and secondary outcome are physical activity score and macronutrient intake.

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Science

#### Expected recruitment start date

2015-10-23, 1394/08/01

#### Expected recruitment end date

2016-03-19, 1394/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2015073116123N6**

Registration date: **2015-10-24, 1394/08/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2015-10-24, 1394/08/02

#### Registrant information

#### Name

Sima Jafarirad

#### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 61 1373 8317

#### Email address

#### Scientific title

Effect of dried black seed grape (vitis vinifera) on clinical and mood symptom in Students with premenstrual syndrome

#### Public title

Dried black seed grape (vitis vinifera) effect on premenstrual syndrome treatment process

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: age 18-35; residence in dormitory; The risk of moderate and severe forms; The lack of any specific treatment to treat PMS; Regular menstrual cycles every 24 to 35 days; Lack of reproductive system diseases; Non-marital. Exclusion criteria: Physical and mental stress in the last three months; Physical illness or medication Consumption; A history of mental illness; Consumption of Antidepressants in recent months; Hormone therapy; Supplements; Having a regular exercise; any specific treatment to treat PMS; Failure to use 80% dried black seed grape during the intervention.

#### Age

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **200**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Using simple random sampling

## Secondary Ids

### 1

**Registry name**

-

**Secondary trial Id**

-

**Registration date**

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

The Ethics Committee of Ahvaz Jundishapur  
University of Medical Science

**Street address**

The Ethics Committee, Vice Chancellor for Research  
and Technology, Ahvaz Jundishapur University of  
Medical Sciences, University City, Golestan blvd.

**City**

Ahvaz

**Postal code**

**Approval date**

2015-08-08, 1394/05/17

**Ethics committee reference number**

IR.AJUMF.REC.1394.371

## Health conditions studied

### 1

**Description of health condition studied**

premenstrual syndrom

**ICD-10 code**

N94.3

**ICD-10 code description**

Premenstrual tension syndrom

## Primary outcomes

### 1

**Description**

Physical symptom score

**Timepoint**

Befor and first and second month end of intervention  
period

**Method of measurement**

Rossignol and Bonnlander standard questionnaire

### 2

**Description**

Mood symptom score

**Timepoint**

Befor and first and second month end of intervention  
period

**Method of measurement**

Rossignol and Bonnlander standard questionnaire

### 3

**Description**

Psychical symptom score

**Timepoint**

Befor and first and second month end of intervention  
period

**Method of measurement**

Rossignol and Bonnlander standard questionnaire

## Secondary outcomes

### 1

**Description**

Physical acyivity score

**Timepoint**

First month and second month after intervention

**Method of measurement**

International physical activity questionnaire

### 2

**Description**

Macro nutrients intake

**Timepoint**

First month and second month after intervention

**Method of measurement**

3-day 24-hour recall

### 3

**Description**

Weight

**Timepoint**

Before and first and second end of intervention period

**Method of measurement**

Balance

#### 4

##### **Description**

Height

##### **Timepoint**

Before and first and second end of intervention period

##### **Method of measurement**

Stadiometer

#### 5

##### **Description**

waist circumference

##### **Timepoint**

Before and first and second end of intervention period

##### **Method of measurement**

Tape measure

#### 6

##### **Description**

Hip circumference

##### **Timepoint**

Before and first and second end of intervention period

##### **Method of measurement**

Tape measure

## **Intervention groups**

#### 1

##### **Description**

Intervention group: Diet controlling; dried black seed grape 90 gram per day, during 7 days before menses, for 2 months.

##### **Category**

Treatment - Other

#### 2

##### **Description**

Control group: Diet controlling, for 2 months.

##### **Category**

Treatment - Other

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Girls dormitories Ahvaz University of Medical Sciences

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

Khadigeh behzadi

###### **Street address**

Student dormitory Golestan

###### **City**

Ahvaz

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

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

Vice Chancellor for Research and Technology,Ahvaz Jundishapur University of Medical Sciences

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

Dr.Nader Saki

###### **Street address**

Vice Chancellor for Research and Technology.Ahvaz Jundishapur University of Medical Sciences,University city,Golestan Blvd.

###### **City**

Ahvaz

##### **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 and Technology,Ahvaz Jundishapur 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**

## **Person responsible for scientific inquiries**

##### **Contact**

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

Nutrition and Metabolic Disease Research Center,Ahvaz Jundishapur University of Medical Science

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

Dr.Sima Jafarirad

###### **Position**

PHD

###### **Other areas of specialty/work**

###### **Street address**

Nutrition and Metabolic Center.Ahvaz Jundishapur University of Medical Sciences,University city,Golestan Blvd.

###### **City**

Ahvaz

###### **Postal code**

###### **Phone**

+98 61 3373 8317

**Fax**  
**Email**  
jafarirad-s@ajums.ac.ir  
**Web page address**

**Phone**  
+98 71 3872 6062  
**Fax**  
**Email**  
sahbehzadi@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz Jundishapur of Medical Science, Paramedics  
School.  
**Full name of responsible person**  
khadigeh Behzadi  
**Position**  
Master Student of Nutrition  
**Other areas of specialty/work**  
**Street address**  
Ahvaz Jundishapur University of Medical  
Sciences, University city, Golestan Blvd. Paramedics  
School  
**City**  
Ahvaz  
**Postal code**

## 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*