

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