Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of pms50 supplement on the psychological symptoms of girls with premenstrual syndrome

Protocol summary

Study aim
Determination of the effect of supplementation of pms50 on psychological symptoms of premenstrual syndrome

Design
The present study is a clinical trial of phase 3, randomized, double-blind, and parallel, which will be performed on 50 girls with premenstrual syndrome who have criteria for entering the study. The participants were randomly assigned to dice Two groups of intervention and control will be divided.

Settings and conduct
This study will be performed on female students of Ahwaz University of Medical Sciences. At first, anthropometric measurements of individuals such as weight, height, BMI, abdomen and Durlegan were measured and a 3-day dietary recall questionnaire and a physical activity questionnaire were recorded. To be The standard Rozgovnol and Bonlander questionnaires were given to individuals, and the questionnaire was followed by a three-day diet.

Participants/Inclusion and exclusion criteria
Entry criteria: single, premenstrual syndrome, regular menstrual cycle, age range 25-35, weight range 55-65kg, normal BMI ranging from18.5 to 24.9 kg/m2.Exit criteria: Marriage, pregnancy, lactation, irregular menstrual cycle, age below 25 or over 35, weight below 55 or above 65kg, taking psychological drugs andUnwillingness of the participant to continue the research

Intervention groups
Participants of female students of Ahvaz University of Medical Sciences were selected for premenstrual syndrome. During the three consecutive menstrual cycles, from one week before menstruation to the end of the menstrual cycle, two tablets (one morning and one night), the supplementary intervention group PMS50 and the placebo control group.

Main outcome variables
Symptoms include restlessness, depression, anger, irritability, transient mood, anxiety and worry, feeling of frustration, loneliness and isolation, feeling unwell, appetite increase or decrease, tenderness to salty or sweet foods

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181218042038N1**
Registration date: **2019-01-15, 1397/10/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-15, 1397/10/25**
Update count: **0**

Registration date
2019-01-15, 1397/10/25

Registrant information

Name
Fatemeh Sadeghi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8802 0649

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-03-19, 1397/12/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pms50 supplement on the psychological symptoms of girls with premenstrual syndrome

Public title

The effect of pms50 supplement on the psychological symptoms of premenstrual syndrom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Unmarried Premenstrual syndrome Regular menstrual cycle Age range 25-35 Weight range 55-65kg Normal BMI ranging from18.5 to 24.9 kg/m2

Exclusion criteria:

Being married Pregnancy Lactation Irregular menstrual cycle Age younger than 25 or over 35 years old Weight below 55 or above 65kg Use of psychological drugs Unwillingness of the participant to continue the research

Age

From **25 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple (assigning a person to a particular group completely randomly) through dice throwing

Blinding (investigator's opinion)

Double blinded

Blinding description

The type of blindness in this study will be double blind. Before starting the study, by dicing throwing by someone other than the researcher, the subjects are in the intervention group and the control group and the supplementary delivery to the patients is also performed by an individual other than the investigator. The study of patients and researcher who plays the role of collecting and analyzing data is kept blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz University of Medical Sciences

Street address

Golestan highway

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.AJUMS.REC.1397.525

Health conditions studied

1

Description of health condition studied

Psychological symptoms of premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

Restlessness score in the Rossignol & Bonlander Questionnaire

Timepoint

The beginning and the end of the study

Method of measurement

Rossignol & Bonlander Questionnaire

2

Description

Depression score in the Russugnol and Bonlander questionnaire

Timepoint

The beginning and the end of the study

Method of measurement

Rossignol & Bonlander Questionnaire

3

Description

Anger Score in the Rossignol & Bonlander Questionnaire

Timepoint

The beginning and the end of the study

Method of measurement

Rossignol & Bonlander Questionnaire

4

Description
Irritability score in the Russugnol and Bonlander questionnaire
Timepoint
The beginning and the end of the study
Method of measurement
Rossignol & Bonlander Questionnaire

5

Description
Anxiety score in the Rossignol & Bonlander Questionnaire
Timepoint
The beginning and the end of the study
Method of measurement
Rossignol & Bonlander Questionnaire

6

Description
Transient mood Score in the Rossignol & Bonlander Questionnaire
Timepoint
The beginning and the end of the study
Method of measurement
Rossignol & Bonlander Questionnaire

7

Description
Feeling frustrated score in the Rossignol & Bonlander Questionnaire
Timepoint
The beginning and the end of the study
Method of measurement
Rossignol & Bonlander Questionnaire

8

Description
Loneliness and isolation score in the Russugnol and Bonlander Questionnaire
Timepoint
The beginning and the end of the study
Method of measurement
Rossignol & Bonlander Questionnaire

9

Description
The score for the lack of attractiveness in the Russugnol and Bonlander questionnaire
Timepoint
The beginning and the end of the study
Method of measurement
Rossignol & Bonlander Questionnaire

10

Description
Increased or decreased appetite score in the Russugnol and Bonlander questionnaire
Timepoint
The beginning and the end of the study
Method of measurement
Rossignol & Bonlander Questionnaire

11

Description
Score the tendency to salty or sweet foods in the Russugnol and Bonlander questionnaire
Timepoint
The beginning and the end of the study
Method of measurement
Rossignol & Bonlander Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Supplement pms50 containing vitamins B1, B2, B6, E, D3, magnesium oxide and Vitagnus extract, two daily pills (one morning and one night) from one week before menstruation to the end of menstruation for three consecutive menstrual cycles
Category
Treatment - Drugs

2

Description
Control group: Placebo, starch, two daily pills (one morning and one night) from one week before menstruation to the end of menstruation for three consecutive menstrual cycles
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Fatemeh sadeghi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad badawi
Street address
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badavi-m@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Fatemeh sadeghi
Position
Masters student
Latest degree
Bachelor
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Person responsible for updating data

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sadeghi.f@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available