

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effectiveness of soft capsule containing anise, sage oil in PMS

Protocol summary

Registration timing: **prospective**

Study aim

Due to prevalence of PMS and adverse effects of current treatments, the effectiveness of soft capsule containing anise oil, sage oil compared with placebo soft capsule on clinical symptoms of PMS

Last update: **2019-04-25, 1398/02/05**

Update count: **0**

Registration date

2019-04-25, 1398/02/05

Design

Double Blind randomized placebo control clinical study

Registrant information

Name

Mohaddese Mahboubi

Name of organization / entity

Tabibdaru

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 1000

Email address

mahboubi1357@yahoo.com

Settings and conduct

Students resident in dominants of Chalus University of Medical Science

Participants/Inclusion and exclusion criteria

90 girls with PMS Students at the ages of 18-35 years old
Students with normal BMI between 18.5-25.9 No smoking
Bleeding duration between 3-10 days in two months before the research
Regular menstruation with cycles of 21-35 days
Confirmation of PMS on the base of PMS questionnaire and daily statement form
No identified psychological diseases
No identified diseases such as diabetes, seizure disorders, hypothyroidism
No death of relatives or accidents during last 6 months
No surgical operation during the last 6 months
Not using of anti-depressant drugs, hormones, contraceptives, medroxy progesterone acetate, vitamins the last three months before the study

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Herbal Soft capsule Placebo Soft Capsule

Main outcome variables

The effects of soft capsule containing anise oil, sage on clinical symptoms (physical and psychological) symptoms of students

Scientific title

Evaluation the effectiveness of soft capsule containing anise, sage oil in PMS

General information

Reason for update

Acronym

PMS

IRCT registration information

IRCT registration number: **IRCT20190306042943N1**

Registration date: **2019-04-25, 1398/02/05**

Public title

Herbal Soft Capsule in treatment of PMS

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Students at the ages of 18-35 years old Students with normal BMI between 18.5-25.9 No smoking Bleeding duration between 3-10 days in two months before the research Regular menstruation with cycles of 21-35 days Confirmation of PMS on the base of PMS questionnaire and daily statement form No identified psychological diseases No identified diseases such as diabetes, seizure disorders, hypothyroidism No death of relatives or accidents during last 6 months No surgical operation during the last 6 months Not using of anti-depressant drugs, hormones, contraceptives, medroxy progesterone acetate, vitamins the last three months before the study

Exclusion criteria:
Incidence of accidents like death of relatives The use of supplements, or vitamins Misuse of drugs, which the patients do not obey the protocol

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is used for patients, and the individuals randomly divided in two groups of intervention and control.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The herbal soft capsules are prepared in formulation unit of Tabib Daru. The placebo soft capsule will prepare by sunflower without effective compound. If the herbal soft capsule have odor, the placebo soft capsules will put near the herbal soft capsule for two weeks

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Department of Midwifry, School of Nursing and Midwifery, Shahid Beheshti Medical Science University

Street address

Iran, Tehran Velenjak St. , Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-02-25, 1397/12/06

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.271

Health conditions studied

1

Description of health condition studied

PMS

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

The severity of psychological and physical symptoms of PMS

Timepoint

Before and after treatments

Method of measurement

Daily Record of Severity of Problems questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 500 mg Soft Capsule containing anise oil, sage oil, twice daily, from the day of 21 menstruation until 2 days after bleeding during two menstrual cycles.

Category

N/A

2

Description

Control group: Placebo
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Calous University of Medical Science

Full name of responsible person

Dr. Masoumeh Simbar

Street address

SBMU School of Nursing & Midwifery, Vali Asr Ave.,
Niayesh Cross Road, Niayesh Complex, Tehran, Iran

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1985717443

Phone

+98 21 8865 5376

Email

msimbar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabib Daru Dez

Full name of responsible person

Dr. Mohaddese Mahboubi

Street address

No 3, Homa building, Motahari Street

City

Kashan

Province

Isfahan

Postal code

8715115815

Phone

+98 31 5554 1000

Email

mahboubi1357@yahoo.com

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabib Daru Dez

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoumeh Simbar

Street address

Shahid Beheshti Medical university School of Nursing
& Midwifery, Vali Asr Ave., Niayesh Cross Road,
Niayesh Complex, Tehran, Iran

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msimbar@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tabibdaru

Full name of responsible person

Mohaddese Mahboubi

Position

Research and Development Manager

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable