

# 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

**City**

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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

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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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**Domestic or foreign origin**

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**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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Homa Building, Motahari Street, Kashan, Iran

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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**Position**  
Research and Development Manager  
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Ph.D.  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Position**  
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**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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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