

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of the effect of *Foeniculum vulgare* fruit and *Echium amoenum* Flower Combination on the severity of Physical and psychological symptoms of premenstrual syndrome

Protocol summary

Study aim

Evaluation of the effect of *Foeniculum vulgare* fruit and *Echium amoenum* Flower Combination on the severity of Physical and psychological symptoms of premenstrual syndrome

Design

Phase 3 randomized triple-blind clinical trial of three witnessed blind groups, including an intervention group and a placebo group

Settings and conduct

The personal information form and PSST will be filled out by women referring to the traditional medicine clinic of Imam Reza Hospital in Mashhad for initial diagnosis. After reviewing the inclusion and non-inclusion criteria, eligible individuals will complete the DRSP for two months. After final confirmation, 80 samples will be randomly selected and complete a quality of life and temperament questionnaire. The permutation block method will be used to assign individuals to study groups. Sequence generation will be by random allocation software. The test group will receive *Echium* and fennel capsules and the control group will receive placebo. The study time is 2 cycles and during it the DRSP is completed.

Participants/Inclusion and exclusion criteria

Inclusion: Age 18 to 35 years Regular menstruation for 6 months Bleeding 3 to 9 and intervals 24 to 35 days Complete the conscious consent form minimum score of 19 from PSST non-Inclusion: History of mental illness, surgery, estrogen-related cancers, thyroid, liver, kidney disease, diabetes, hypertension Death of a loved one in the last six months use of anti-anxiety and anti-depressant, estrogen and progesterone drugs in the last three months Taking herbal, vitamin and mineral supplements over the past month allergy to *Echium* and fennel Pregnancy, lactation

Intervention groups

Intervention: capsules (with a dose of 2 grams of *Echium* and 1 gram of fennel per day), in the second two weeks, In two cycles. placebo: starch capsule

Main outcome variables

The rate of changes in the severity of symptoms of PMS

General information

Reason for update

The closure of the dormitories due to the prevalence of COVID-19 caused a change in the sampling location, followed by a change in the entry criteria (being single) and the non-entry criteria (pregnancy and lactation). Due to the termination of the previous statistics consultant's cooperation with the university and the change of the consultant, the change of randomization method and statistical software was done according to his opinion. For ease of swallowing by the patient, the volume of capsules was reduced and the dose was increased.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200530047600N1**

Registration date: **2020-07-18, 1399/04/28**

Registration timing: **prospective**

Last update: **2021-09-21, 1400/06/30**

Update count: **1**

Registration date

2020-07-18, 1399/04/28

Registrant information

Name

Simin sadat Motevalli Haghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3891 0394

Email address

Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Foeniculum vulgare fruit and Echium amoenum Flower Combination on the severity of Physical and psychological symptoms of premenstrual syndrome

Public title

Evaluation of the effect of Foeniculum vulgare fruit and Echium amoenum Flower Combination on the severity of Physical and psychological symptoms of premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 35 years Regular menstruation for the past 6 months, Bleeding period 3 to 9 days and two bleeding intervals 24 to 35 days, Complete the conscious consent form Get a minimum score of 19 from the PSST questionnaire

Exclusion criteria:

History of mental illness, surgery, estrogen-related cancers, thyroid, liver and kidney disease, diabetes and hypertension Death of a loved one in the last six months The use of anti-anxiety and anti-depressant drugs in the last three months, The use of estrogen and progesterone medications in the last three months, Taking herbal medicines and vitamin and mineral supplements over the past month, History of allergy to Echium and fennel Pregnancy and lactation

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization Unit: Individual It is not stratified Tools: random allocation statistical software Regarding concealment: A person outside the design will prepare sealed envelopes based on the random allocation sequence created and provide them to the executors.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The same capsules, with the same number, are placed in similar enveloped envelopes (from 1 to 80) based on a random assignment list by a person outside the research design. The study subjects receive the capsules monthly and in envelopes with the code. Participants, researchers, data evaluators, and data analysts are unaware of how the code is assigned.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Research of Mashhad University of Medical Sciences

Street address

Ethics Committee in Research, Central University Building, University Street

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Mashhad

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Razavi Khorasan

Postal code

9138813944

Approval date

2020-05-23, 1399/03/03

Ethics committee reference number

IR.MUMS.REC.1399.276

Health conditions studied**1****Description of health condition studied**

Premenstrual Syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

The rate of change in the severity of symptoms of premenstrual syndrome

Timepoint

Before the intervention, the first menstrual cycle after the intervention, the second menstrual cycle after the intervention

Method of measurement

Daily Record of Severity of Problems (DRSP)

Secondary outcomes

1

Description

The relationship between general temperament and the severity of symptoms

Timepoint

At the beginning of the study

Method of measurement

Daily Record of Severity of Problems (DRSP), Mojahedi Mizaj Questionnaire(MMQ)

2

Description

Changes in the quality of life in the intervention and control groups

Timepoint

Before and after the intervention

Method of measurement

Short-Form Health Survey questionnaire(SF-36)

3

Description

possible side effects

Timepoint

During the intervention

Method of measurement

Patient report

4

Description

The relationship between general temperament and the type of symptoms

Timepoint

At the beginning of the study

Method of measurement

Daily Record of Severity of Problems (DRSP), Mojahedi Mizaj Questionnaire(MMQ)

Intervention groups

1

Description

Intervention group: The test group received oral capsules containing Echium and fennel at a dose of 2 grams of Echium and 1 gram of fennel fruit (Ground and granulated) during the day, three times a day with a glass of lukewarm water for the second two weeks of Cycle in two consecutive cycles.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive a placebo capsule containing starch with the conditions of the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Traditional medicine clinic of Imam Reza Hospital

Full name of responsible person

Simin Sadat Motevalli Haghi

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Margin of Imam Reza (AS) Square, Ibn Sina St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghadi

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University Street, next to Hoveyze Cinema, Ghorashi Building, Deputy of Research and Technology

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

Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Simin Sadat Motevalli Haghi

Position
PhD student

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Person responsible for updating data

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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

