Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

motevalihs961@mums.ac.ir

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
City
Mashhad
Province
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghadi
Street address
University Street, next to Hoveyzeh 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

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