Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation the effect of wheat germ extract capsules on the severity of Premenstural symptomes in women employed in hospitals in Hamadan

Protocol summary

Summary

This study aims to determine the effects of wheat germ extract capsules on premenstural syndrome symptoms in women employed in hospitals affiliated to Hamedan University of Medical Sciences. Inclusion criteria: age should be between 20 and 45 years; BMI should be between 19/8 and 26; they should be non smokers. they should have 3 to 10 days bleeding in two months prior to study; Regular menstrual cycles should be 21-35 days; premenstural syndrome based on pre menstural syndrome provisional diagnosis questionnaire and daily form showing premenstural syndrome symptoms after 2 months should be proved; they should have no known mental illnesses; they should have no physical illnesses such as diabetes, seizure disorders, hypothyroidism and so on; There should be no death of close relatives, divorce or other adverse events in the last 3 months; Surgery should not be performed in the three months before entering study; Antidepressants, hormonal contraceptives, medroxy progesterone acetate, and vitamins should not be taken in the past three months; Exclusion criteria: pregnancy, incidents like the death of close relatives, divorce, and other adverse events; taking 3 capsules of wheat germ or less on two consecutive days, taking supplements, eating wheat germ. this study is done using triple blind, controlled clinical trial method on 84 women working in the morning shift at the hospital in Hamadan. participants complete daily symptom record form for two consecutive months and after definitive diagnosis of premenstural syndrome are randomly divided into two groups of 42 and for two consecutive months, they take 400 mg capsules of wheat germ extract 3 times daily from day 16 of menstrual cycle untill day 5 of menstrual cycle. Data are analyzed using SPSS-17 and descriptive statistics to assess the severity of premenstural syndrome.

General information

Acronym

Premenstural syndrom

IRCT registration information

IRCT registration number: **IRCT201310286807N8**
Registration date: **2013-12-21, 1392/09/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-12-21, 1392/09/30

Registrant information

Name

Sedigheh Amir Ali Akbari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2272 9240

Email address

akbarisedd@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation the effect of wheat germ extract capsules on the severity of Premenstural symptomes in women employed in hospitals in Hamadan

Public title
Effect of wheat germ juice on premenstural syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age should be between 20 and 45 years; BMI should be between 19/8 and 26; they should be non smokers; they should have 3 to 10 days bleeding in two months prior to study; Regular menstrual cycles should be 21-35 days; premenstural syndrome based on premenstural syndrome provisional diagnosis questionnaire and daily form showing premenstural syndrome symptoms after 2 months should be proved; they should have no known mental illnesses; they should have no physical illnesses such as diabetes, seizure disorders, hypothyroidism and so on; There should be no death of close relatives; divorce or other adverse events in the last 3 months; Surgery should not be performed in the three months before entering study; Antidepressants, hormonal contraceptives, medroxy progesterone acetate, and vitamins should not be taken in the past three months; Exclusion criteria: pregnancy; incidents like the death of close relatives, divorce, and other adverse events; taking 3 capsules of wheat germ or less on two consecutive days; taking supplements; eating wheat germ.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of International branch of Shahid Beheshti University of Medical Sciences

Street address
Tehran, next to Hemmat Bridge, International branch of Shahid Beheshti University of Medical Sciences

City
Tehran

Postal code

Approval date
2013-10-07, 1392/07/15

Ethics committee reference number
116/2879

Health conditions studied

1

Description of health condition studied
pre menstural syndrome

ICD-10 code
N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Severity of pre menstural syndrome

Timepoint
8 weeks Before treatment, 8 weeks after treatment

Method of measurement
Diagnostic and Statistical Manual of Mental Disorders, 4th. Edition

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: wheat germ extract, capsules, 400 mg orally, three times a day for two months

Category
Treatment - Drugs

2

Description
Control group: Starch, Capsule 400 mg orally three times a day for two consecutive months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Mr. Kazemi
Street address
Hamadan, next to the station, the prison turn, Farshchian Hospital
City
Hamedan

2

Recruitment center
Name of recruitment center
Boali Hospital
Full name of responsible person
Mrs. Shahidi
Street address
Hamadan, next to Luna park, Boali Hospital
City
Hamadan

3

Recruitment center
Name of recruitment center
Ekbatan Hospital
Full name of responsible person
Mr.Bagheri
Street address
Hamadan, University Square, Ekbatan Hospital
City
Hamadan

4

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Mr.Shahrokhi
Street address
Hamadan, Besat Hospital
City
Hamadan

5

Recruitment center
Name of recruitment center
Beheshti Hospital
Full name of responsible person
Mr.Zolhavarie
Street address
next to Luna park, Eram Blvd, Beheshti Hospital
City
Hamedan

6

Recruitment center
Name of recruitment center
Fatemiyyeh Hospital
Full name of responsible person
Mrs. Abubzade
Street address
Kermanshah Street, Fatemiyyeh Hospital
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Kiandokht Ghanati
Street address
Tehran, next to Hemmat Bridge, International branch of Shahid Beheshti University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seddighe Amir Ali Akbari
Position
Msc
Other areas of specialty/work
Street address
Tehran, Niayesh, Shahid Beheshti University of Medical Sciences
City
Tehran
Postal code
1996835119
Phone

+98 21 8820 2512

Fax

+98 21 2272 9238

Email

asa_akbari@yahoo.com

Web page address

sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seddighe Amir Ali Akbari

Position

Msc

Other areas of specialty/work

Street address

Tehran, Niayesh, School of Nursing and Midwifery

City

Tehran

Postal code

1996835119

Phone

+98 21 8820 2512

Fax

+98 21 2272 9238

Email

asa_akbari@yahoo.com

Web page address

sbmu.ac.ir

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty