

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation the effect of wheat germ extract capsules on the severity of Premenstrual symptoms in women employed in hospitals in Hamadan

Protocol summary

Summary

This study aims to determine the effects of wheat germ extract capsules on premenstrual 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; premenstrual syndrome based on pre menstrual syndrome provisional diagnosis questionnaire and daily form showing premenstrual 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 premenstrual 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 premenstrual syndrome.

General information

Acronym

Premenstrual 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 Premenstrual symptoms in women employed in hospitals in Hamadan

Public title

Effect of wheat germ juice on premenstrual 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; premenstrual syndrome based on premenstrual syndrome provisional diagnosis questionnaire and daily form showing premenstrual 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 menstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes**1****Description**

Severity of pre menstrual 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

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Person responsible for scientific inquiries

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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