

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of flaxseed oil compared with placebo on premenstrual dysphoric disorder: a double-blind randomized controlled clinical trial

Protocol summary

Summary

The purpose of this study is to evaluate the effect of flaxseed oil for relief the symptoms of premenstrual syndrome. The study is a randomized, double-blind which will be carried out on 118 patients with premenstrual dysphoric disorder referred to Ziaei Hospital. The study will be conducted on women 18 to 35 years with premenstrual dysphoric complaint that not received any other drugs and effective supplements on premenstrual syndrome 2 months before intervention and have no other mental or physical illness during 3 months before study and will be excluded if side effects and drug intolerance occurs. Method: With simple randomization, patients will be divided into 2 groups: intervention group (flaxseed oil soft gel) and control group (placebo soft gel). All patients will receive flaxseed oil or placebo soft gel over 3 menstrual cycles from 7 days before starting cycle for 14 days twice a day. Response to treatment and possible side effects are examined by the relevant questionnaire. All patients and researchers are blinded to the study groups and information on groups studied will be specified at the end of the study and statistical analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040227170N1**

Registration date: **2017-06-27, 1396/04/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-27, 1396/04/06

Registrant information

Name

Fatemeh Nejatbakhsh

Name of organization / entity

medical University Tehran

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran university School of Traditional Medicine

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of flaxseed oil compared with placebo on premenstrual dysphoric disorder: a double-blind randomized controlled clinical trial

Public title

The effect of flaxseed oil on premenstrual dysphoric disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 and 35; Regular menstrual cycles (21-35 days) in the past two months; No smoking, tobacco and drugs; Have premenstrual

dysphoric disorder according to PSST questionnaire; No use of other drugs and effective supplementation on premenstrual syndrome for 2 months before intervention; Not taking oral contraceptives; No history of psychiatric drugs and psychotropic substances in the past 6 months; No history of physical or mental illness during 3 months before study; No depression based on the SCL-90-R; No stress in the last three months like dead relatives or marriage or surgery, No pregnancy; No lactating Exclusion criteria: consumption of other drugs and supplements effective in the treatment of premenstrual syndrome during study; oral contraceptive pills during intervention; Report any allergies or side effects during the study; Inappropriate use of drugs; get pregnant; Cancel study

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **118**

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**

Ethics Committee of Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical Sciences, near Quds St., Keshavarz Ave.

City

Tehran

Postal code**Approval date**

2016-01-06, 1394/10/16

Ethics committee reference number

IR.TUMS.REC.1394.1576

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

Premenstrual dysphoric disorder

ICD-10 code

F32.81

ICD-10 code description

An affective disorder manifested by either a dysphoric mood or loss of interest or pleasure in usual

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

Premenstrual dysphoric disorder severity

Timepoint

before and during the three months of intervention

Method of measurement

PSST questionnaire

Secondary outcomes**1****Description**

Response to treatment

Timepoint

After intervention

Method of measurement

CGI-I questionnaire

2**Description**

Patient satisfaction

Timepoint

After intervention

Method of measurement

Questionnaire

Intervention groups**1****Description**

All patients in first intervention group, taking Flaxseed oil soft gel over three menstrual cycles from 7 days before starting cycle for 14 days, fasting and before sleep

Category

Treatment - Drugs

2**Description**

All patients in second intervention group, taking placebo soft gel over three menstrual cycles from 7 days before starting cycle for 14 days, fasting and before sleep

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's clinic of Ziaieian Hospital

Full name of responsible person

Street address

Opposite municipality 17, 20 m Abuzar, Abuzar Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran university
School of Traditional Medicine

Full name of responsible person

Roja Rahimi

Street address

No 27, Corner Alley Tabriz, Sarparast Shomali Str,
Taleghani Ave

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 Tehran university School
of Traditional Medicine

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

Tehran University of medical sciences

Full name of responsible person

Fereshteh Ghorat

Position

PhD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Assistant Professor

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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