

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of Primerose oil on Premenstrual syndrome

Protocol summary

Research center of Lorestan University of Medical Sciences

Summary

In this clinical trial, we determine the effect of primrose oil on the premenstrual syndrome. A total of 80 ladies aging 18 - 35 with the regular period of 24 - 30 days are recruited. They are randomly assigned into intervention or control group. The intervention group receives 1500 mg, 3 500 mg capsules, daily for 12 weeks) while the control group receive placebo. The severity of symptoms between two groups are measured using a measure rating 0 - 10, once monthly for 3 months, by a Obstetric and Gynecologist and compared between groups.

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Scientific title

The effect of Primerose oil on Premenstrual syndrome

Acronym

IRCT registration information

IRCT registration number: **IRCT201009214789N1**

Registration date: **2010-12-01, 1389/09/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-01, 1389/09/10

Registrant information

Name

Mandana Saki

Name of organization / entity

Lorestan Unuversity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 1620 0140

Email address

saki.m@mail.lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Public title

The effect of Primerose oil on Premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 - 35, having regular menstrual cycles with intervals 24 - 35 days , Without any physical diseases or specific drugs use, Analgesia drug for relieving pain , no record of mental diseases specially Depression disorder, no use of any anti depressants or hormonal drugs, no specific diet, no experience of stressful event during last 3 month from the beginning of the study and during the study Exclusion criteria: Occurrence of the event during the study, having physical or mental diseases, pregnancy, lactation, menstrual cycle irregularity, medical diseases, using hormonal method of contraception

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, Pardis
Medical Campus, Kamalvand , ,

City

Khorram Abad

Postal code

381351698

Approval date

2010-05-19, 1389/02/29

Ethics committee reference number

27946/200--22/5/2010

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

Intensity of the premenstrual syndrome

Timepoint

monthly during a period of 3 months

Method of measurement

The determination of total grade (for any symptom from
0-10)

Secondary outcomes

empty

Intervention groups

1

Description

Primerose oil capsule, 1500 mg/day (500 mg, TDS) for
12 weeks

Category

Treatment - Drugs

2

Description

Placebo capsule (TDS) for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Lorestan University of Medical Sciences dormitories

Full name of responsible person

Mandana Saki

Street address

Faculty of nursing and midwifery, Pardis Medical
Campus, Kamalvand

City

Khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi Herbal Drugs Research Center, Deputy of
Research and Information Technology, Lorestan
Universit

Full name of responsible person

Dr. Bahram Rasoulia

Street address

Razi st, Enghelab Avenue, Khorramabad, Lorestan,
Iran

City

Khorram Abad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Razi Herbal Drugs Research Center, Deputy of Research
and Information Technology, Lorestan Universit

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***Postal code**

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Position

MSc - Psychiatric nursing - faculty member

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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*