Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Primerose oil on Premenstrual syndrome

Protocol summary

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.

General information

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
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Iran (Islamic Republic of)
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+98 66 1620 0140
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saki.m@mail.lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research center of Lorestan University of Medical Sciences

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

Scientific title

The effect of Primerose oil on Premenstrual syndrome

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
premenstural 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 Rasoulian
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

Person responsible for general inquiries

Contact
Name of organization / entity
Lorestan University of Medical Sciences
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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