Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Evening prime rose oil and vitamin E on reduction of symptoms of premenstrual syndrom.

Protocol summary

Summary

To determine the effect of vitamin E and Evening primrose oil therapy in the treatment of premenstrual syndrom. Design: Double blinded randomized clinical trials. 70 health connectors who eligible for inclusion criteria will be recruited to this study. Thease people will randomly divided to two groups. Intervention: The intervention group for two consecutive cycles, at least 14 days before menstruation, will receive three capsules of Evening primrose oil therapy (per capsule 1000 mg) in 3 dose daily. Control: In control group one capsule of Vitamin E 400 UI in luteal phase of cycle will use daily. Primary outcome:physical symptom of pre menstrual syndrom. Secondary outcome: mental symptom of premenstrual syndrom.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061313405N2**
Registration date: **2014-01-06, 1392/10/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-01-06, 1392/10/16

Registrant information

Name
Seyyedeh Zahra Masoumi
Name of organization / entity
Hamedan University of Medical Sciences, School of Nursing and Midwifery
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Evening prime rose oil and vitamin E on reduction of symptoms of premenstrual syndrom.

Public title

Comparison of Evening prime rose oil and vitamin E on reduction of symptom of premenstrual syndrom.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a) Women in age between 18-30 years old; b) Having regular menstrual cycles every 35-24 days; c) Lack of physical or medication illness; d) No history of mental illness and depression; e) lack of antidepressant use in the past months f) Suffering from premenstrual syndrom. Exclusion study: a) Any use of hormonal and vitamin drugs or contraceptive pills; b) Experience of the spiritual crisis or death of a family member or surgery in the last three months ago.

Age

From **18 years** old to **30 years** old

Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamedan University of Medical Sciences
Street address
Vice chancellor for research and technology,Hamedan University of Medical Sciences,Fahmideh Ave,Hamedan
City
Hamedan
Postal code
6517838695
Approval date
2013-05-05, 1392/02/15
Ethics committee reference number
16/35/9/262/د/پ

Health conditions studied

1

Description of health condition studied
Pre menstrual syndrom
ICD-10 code
F39
ICD-10 code description
Unspecified mood [affective] disorder

Primary outcomes

1

Description
physical symptom of pre menstrual syndrom.
Timepoint
Before intervention- immediately after intervention- 2 months after intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
mental symptom of pre menstrual syndrom.
Timepoint
Before intervention-immediatly after intervention-2 months after intervention
Method of measurement
A questionnaire based on DSM-IV research criteria and demographic questionnaire.

Intervention groups

1

Description
The intervention group for two consecutive cycles, at least 14 days before menstruation, will receive three capsules of Evening primrose oil therapy (per capsule 1000 mg) in 3 dose daily and in group II (n = 35) one capsule of Vitamin E 400 UI daily in luteal phase of cycle will use.
Category
Treatment - Drugs

2

Description
In control group one capsule of Vitamin E 400 UI daily that similar to prime rose oils capsules in luteal phase of cycle for two months will use.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hossein health center of Hamedan
Full name of responsible person
Zahra Shojaee
Street address
2nd station,Behind of Bazare Rooz,Khezr,Hamedan
City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research the Technology, Hamedan University of Medical Sciences

Full name of responsible person
Dr Saeed Bashiriyan

Street address
Vice chancellor for research and technology,Hamedan university of Medical Sciences,Fahmideh Ave,Hamedan

City
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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 the Technology, Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Seyyedeh Zahra Masoumi

Position
Instrucror

Other areas of specialty/work

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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