Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of omega-3 and rose extract treatment of premenstrual syndrome in women with dysmenorrhea who referred to Taleghani Hospital, Arak

Protocol summary

Summary

This clinical trial is a study on women is referred to Taleghani Hospital of Arak. Random sample of 120 person, Which randomly and using form provisional diagnosis of premenstrual syndrome occurs (Wong-Baker faces pain rating scale (WBS).Inclusion criteria: Age 18-30 years, Regular menstrual periods with long intervals of 21-35 days, BMI:8/19-26, No smoking, Lack of contraceptive pills, The absence of Allergy to fish or fish oil or herbal medicines. Exclusion criteria: Self-medication, The study of non-compliance with medication orders. Selected individuals will be placed randomly in three groups. Group the first 14 days before the onset of menstruation, subsequent to menopause, daily A capsules 500 mg omega-3 and the second group during 14 days before the time of menarche until menopause, 30 drops of Oral drops of rose will be given .Third group as control and will not receive the drug. Patients in this group are not well-justified self-treatment and in this case will be excluded. Intervention will be conducted in three successive cycles. Form in the patient's symptoms can be completed on a daily basis. The index is calculated using SPSS software and t test Analysis was central and dispersion. The aim is to study the effect of treatment rose extracts and omega-3 can be proposed using these drugs improve quality of life in women with lower cost and reduced side effects.

General information

Acronym

PMS:Pre-Menstrual Syndrome

IRCT registration information

IRCT registration number: **IRCT201108237405N1**
Registration date: **2012-05-09, 1391/02/20**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-05-09, 1391/02/20

Registrant information

Name
Dr Sanaz Mirzae
Name of organization / entity
Arak University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Arak University Of Medical Sciences

Expected recruitment start date

2012-04-08, 1391/01/20

Expected recruitment end date

2014-03-16, 1392/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of omega-3 and rose extract treatment of premenstrual syndrome in women with dysmenorrhea who referred to Taleghani Hospital, Arak

Public title

Comparison of the therapeotic effects of omega3 fatty

acids and Rose damascena on premenstural syndrom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 30 years old; regular menstrual periods with long intervals of 21-35 days; body mass index between 19.8 to 26; no history of smoking; not using contraceptive pills, anticonvulsants, antidepressants and vitamins during last 3 months; no history of mental illness and physical context (diabetes, hyperthyroidism and hypothyroidism, etc.); absence of symptoms such as tingling, Itching or abnormal vaginal discharge; no allergy to fish or fish oil or herbal medicines; no incident occurred in the past 6 months and diagnosis of premenstrual syndrome by using form syndrome diagnostic criteria for temporary. Exclusion criteria: unwillingness to continue their treatment and non-compliance with medication orders during the study.

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: **120**

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

Ethic Committee Of Arak University Of Medical Sciences

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Postal code

3819693345

Approval date

2012-02-27, 1390/12/08

Ethics committee reference number

7-121-90

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

Pain Intensity

Timepoint

During The next 14 days before the time of menarche to menopause

Method of measurement

Questionnaire Wong-Baker faces pain rating scale(WBS)

2

Description

Tension

Timepoint

During the next 14 days before the time of menarche to menopause

Method of measurement

Questionnaire Wong-Baker faces pain rating scale(WBS)

3

Description

Depression

Timepoint

During the next 14 days before the time of menarche to menopause

Method of measurement

Questionnaire Wong-Baker faces pain rating scale(WBS)

4

Description

Sleep Disorder

Timepoint

During the next 14 days before the time of menarche to menopause

Method of measurement

Questionnaire Wong-Baker faces pain rating scale(WBS)

Secondary outcomes

empty

Intervention groups

1

Description
In the second group during 14 days before the start of the next menstruation to end of menstruation, the daily will be 30 drops (15 drops twice a day) Rose Oral Drop (Barij Essence company)

Category
Treatment - Drugs

2

Description
In the first group during the 14 days before the start of the next menstruation to menopause, a daily 500 mg of omega 3(Blooms build Australia's brand, company Baryj Essence)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani Hospital

Full name of responsible person
Dr Sanaz Mirzae

Street address
Taleghani Hospital Arak

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University Of Medical Sciences

Full name of responsible person
Dr Saed Changizi Ashtiyani

Street address
A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City
Arak

Grant name

Grant code / Reference number

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

Title of funding source
Arak 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
Arak Univesity of Medical Sciences

Full name of responsible person
Dr Sanaz Mirzae

Position
MD, Resident of Obstetrics And Gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Taleghani Hospital

Full name of responsible person
Dr Mehri Jamilian

Position
Assistant Professor of Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

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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