Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of treatment with dydrogesterone or calcium plus vitamin D on the severity of premenstrual syndrome

Protocol summary

Summary

Objective: To compare the effects of dydrogesterone and Calcium plus Vitamin D on women with severe premenstrual syndrome (PMS). Method: In this randomized, double-blind, placebo-controlled study, 180 Shiraz University students with PMS recruited. They completed questionnaires to record their symptoms for 2 menstrual cycles. Then, the students were randomly assigned to take one of interventions including: 5 mg of dydrogesterone, 500 mg of calcium plus 200 mg of vitamin D, or a placebo twice daily from the 15th to the 24th day of the cycle for 2 more cycles. They completed the same questionnaires during the intervention cycles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711201548N2**
Registration date: **2009-09-09, 1388/06/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-09-09, 1388/06/18

Registrant information

Name
Khadijeh Abdali
Name of organization / entity
Fatemeh college of nursing and midwifery, Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Deputy for Research of Shiraz University of Medical Sciences

Expected recruitment start date

2008-02-03, 1386/11/14

Expected recruitment end date

2009-03-04, 1387/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of treatment with dydrogesterone or calcium plus vitamin D on the severity of premenstrual syndrome

Public title

Comparison of the effect of dydrogesterone and calcium plus vitamin D on the severity of premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (1) having regular menstrual cycles (3–8 days of menstruation between intervals of 22–35 days); (2) not taking medications such as hormonal contraceptives, antipsychotics, or vitamins; (3) not having contraindications to taking dydrogesterone or supplements containing calcium or vitamin D; (4) meeting the American College of Obstetrics and Gynecology and American Psychiatric Association standard diagnostic criteria for PMS (5 or more symptoms present for most of the time during the 7–10 days prior to menstruation; symptoms beginning to remit a few days after the onset of the follicular phase and absent in the week following the menses; and at least 1

symptom in the psychotic domain); (5) diagnostic criteria confirmed by prospective daily symptom ratings during at least 2 consecutive cycles; (6) symptoms markedly interfering with work or school activities and relationships; (7) symptoms not merely an exacerbation of another condition such as epilepsy or a major depressive disorder, panic disorder, or personality disorder; and (8) not using daily foods containing a great deal of calcium and/or vitamin D.

Age
From **18 years** old to **26 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **180**

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
Medical Research Ethics Committee of Shiraz University of Medical Sciences

Street address
Zand St.

City
Shiraz

Postal code

Approval date
2008-02-03, 1386/11/14

Ethics committee reference number
86-3812

Health conditions studied

1

Description of health condition studied
Severity of premenstrual syndrome

ICD-10 code
N94

ICD-10 code description
Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description
Severity of premenstrual syndrome

Timepoint
one month

Method of measurement
Daily symptom rating questionnaire

Secondary outcomes

1

Description
decrease in the severity of premenstrula syndrome

Timepoint
one month

Method of measurement
questionnaire of daily symptom rating

Intervention groups

1

Description
Dydrogesterone,twice daily from the 15th to the 24th day of the menstrual cycle

Category
Treatment - Drugs

2

Description
Calcium D, twice daily from the 15th to the 24th day of the cycle

Category
Treatment - Drugs

3

Description
Placebo: twice daily from the 15th to the 24th day of the cycle

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz University

Full name of responsible person

Street address

Eram sq.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy for Research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Mohammad Hosein Dabbagh Manesh

Street address

Zand st.

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy for Research of Shiraz 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Fatemeh College of Nursing and Midwifery, Shiraz

Full name of responsible person

Khadijeh Abdali

Position

Master's degree in Midwifery, Faculty member

Other areas of specialty/work

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Full name of responsible person

Khadijeh Abdali

Position

Other areas of specialty/work

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City

Postal code

Phone

Fax

Email

Web page address

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