

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluating the Effects of vitamin d and vitamin e on the Severity of Premenstrual Syndrome in the affected persons that go to medical-health centers of isfahan university of medical sciences

Protocol summary

Summary

Object:The objective of the current study is to determine the effect of vitamin D, vitaminE, and the placebo on the severity of PMS in the patients affected by the disease referred to the health centers of Isfahan University of Medical Sciences. **Design:**The present study study is double blind randomized three groups clinical trial. **Setting and conduct:** One hundred and fifty of PMS affected women were randomly selected and when the diagnosis was confirmed,assigned to each three group(vitamin D and vitamin E and placebo).Medical intervention was carried out in two menstrual cycles and the results of pre- and post-test were compared. **Participants including major eligibility criteria:** being 15-45 years old; having regular menstrual cycle; not being affected by depression or anxiety; not having an acute or chronic disease; not taking medicines or supplements; and not taking regular exercise.The **exclusion criteria:** pregnancy; willingness to use hormonal contraceptive methods or taking any hormonal treatment; not taking the drug or not filling out the forms regularly; and unwillingness to continue the treatment. **Intervention:** Daily consumption of Vitamin D(Containing 200 mg of powdered vitamin D of MERK company, prepared by Isfahan Faculty of Pharmacy)or vitamin E(Containing 100 mg of powdered vitamin E of MERK company, prepared by Isfahan Faculty of Pharmacy) or placebo(Containing of Starch, prepared by Isfahan Faculty of Pharmacy) from the first day of the menstrual cycle until the first day of the next menstrual cycle for 2 cycles. **main outcome measures variables:**The mean score of premenstrual syndrome

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401086854N2**

Registration date: **2014-05-19, 1393/02/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-19, 1393/02/29

Registrant information

Name

Elham Ebrahimi

Name of organization / entity

Azad University

Country

Iran (Islamic Republic of)

Phone

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Email address

ebrahimi_308@yahoo.com

Recruitment status

Recruitment complete

Funding source

Funding for this research was provided by the Research Council of Isfahan University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2011-12-21, 1390/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effects of vitamin d and vitamin e on the Severity of Premenstrual Syndrome in the affected persons that go to medical-health centers of isfahan university of medical sciences

Public title

Effect of vitamin d and vitamin e on premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being 15-45 years old; having regular menstrual cycle; not being affected by depression or anxiety; not having an acute or chronic disease; not taking medicines or supplements, and not taking regular exercise The exclusion criteria: pregnancy; willingness to use hormonal contraceptive methods or taking any hormonal treatment; not taking the drug or not filling out the forms regularly; and unwillingness to continue the treatment.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

Ethical comitee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjarib St,Azadi Squ, Isfahan, Iran.

City

Isfahan

Postal code

Approval date

2011-09-06, 1390/06/15

Ethics committee reference number

290147

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

Mean score of syndrome

Timepoint

2 months before and 2 montha after

Method of measurement

Daily Rating Test

Secondary outcomes

1

Description

Side effect

Timepoint

2 months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Daily consumption of Vitamin D(Containing 200 mg of powdered vitamin D of MERK company, prepared by Isfahan Faculty of Pharmacy)or vitamin E(Containing 100 mg of powdered vitamin E of MERK company, prepared by Isfahan Faculty of Pharmacy) from the first day of the menstrual cycle until the first day of the next menstrual cycle for 2 cycles.

Category

Treatment - Drugs

2

Description

Daily consumption of the placebo(Containing of Starch, prepared by Isfahan Faculty of Pharmacy) from the first day of the menstrual cycle until the first day of the next menstrual cycle for 2 cycles.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Navabe Safavi and Ebne Sina health centers

Full name of responsible person

Nahid Fathizadeh

Street address

Navabe Safavi health center, Bozorgmehr squ,
Isfahan,Iran.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Isfahan University of
Medical Sciences

Full name of responsible person

Nahid fathizadeh

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Isfahan University of Medical Sciences, Hezarjarib
St,Azadi Squ, Isfahan, Iran.

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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,Isfahan 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

Shahrood University Of MedicalSciences.

Full name of responsible person

Elham Ebrahimi

Position

Phd candidated of reproductive health

Other areas of specialty/work**Street address**

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Msc

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Position

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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