Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

+98 22 1522 3903

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
Questionaire

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

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

City
Isfahan

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
Shahrood University Of Medical Sciences,Hafte Teer Square, Shahroud, Iran

City
Shahrood

Postal code

Phone
+98 21 7631 0158

Fax

Email
Ebrahimi_308@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Nahid Fathizadeh

Position
Msc

Other areas of specialty/work

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

City
Isfahan

Postal code

Phone
+98 913 100 4312

Fax

Email
Ebrahimi_308@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahrood University Of Medical Sciences

Full name of responsible person
Elham Ebrahimi

Position
Phd condidated of reproductive health

Other areas of specialty/work

Street address
Shahrood University Of Medical Sciences, Hafte Teer Square, Shahrood, Iran.

City
Shahrood

Postal code

Phone
+98 936 548 9806

Fax

Email
EBRAHIMI_308@YAHOO.COM

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