Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

comparison of magnesium,vitamin b6 and b6-magnesium combination on premenstrual syndrome in the affected persons that going to medical health centers of isfahan university

Protocol summary

Summary

Design and methods: The study population will be women of 15-45, referred to the selected health centers, who will be affected by the PMS according to the criteria of American Psychiatry Association, and also met the 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 medicine or supplements; and not taking regular exercise). The exclusion criteria will be pregnancy; willingness to use hormonal contraceptive methods or taking hormonal treatment; not taking the drug or not filling out the forms regularly; and unwillingness to continue the treatment. The patients will be randomly assigned to two intervention groups and one control group. The study will be carried out for four months in ten selected health centers in Isfahan. The primary health measure in this study is premenstrual syndrome severity that will be recognized by scoring on daily symptoms test. To confirm the PMS diagnosis in patients, they will be asked to fill out the PMS daily symptom record form for two months and then .when the diagnosis will be confirmed, the patients will be randomly assigned to one of the four groups of the study) magnesium, vitamin B6,B6- magnesium and placebo).Medical intervention in the shape of consuming one tablet in the day, will be carried out in two menstrual cycles and the result of pre- and post-test will be compared. The type of consuming material in this assay will be magnesium oxide (MgO) and pyridoxine powder that produced by MERK company and Drug faculty of Isfahan University will make these productions in the shapes of 250 milligram magnesium tablet, 40 milligram vitamin B6 tablet and 250 milligram magnesium +40 milligram vitamin B6 .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106216854N1**
Registration date: **2011-07-19, 1390/04/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-19, 1390/04/28

Registrant information

Name
Elham Ebrahimi
Name of organization / entity
Azad University
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2010-04-14, 1389/01/25

Expected recruitment end date

2010-09-16, 1389/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
comparison of magnesium,vitamin b6 and b6-magnesium combination on premenstrual syndrome in the affected persons that going to medical health centers of isfahan university

Public title
determining the effect of magnesium,vitamin b6 and b6-magnesium combination on premenstrual syndrome in the affected persons that going to medical health centers of isfahan university

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criterial: The study population will be women of 45-15 referred to the selected health centers; who were affected by the PMS according to the criteria of American Psychiatry Association; and also met the inclusion criteria; being 45-15 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) exclusion criterial: will be pregnancy; willingness to use hormonal contraceptive methods or taking 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

Groups that have been masked
No information

Sample size
Target sample size: **170**

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 Committee of Isfahan University of Medical Sciences

Street address
Isfahan university of medical science, Hezarjarib street, Isfahan, Iran

City
Isfahan

Postal code

Approval date
2010-03-14, 1388/12/23

Ethics committee reference number
388554

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
premenstrual syndrome severity

Timepoint
2 month before and 2 month after intervention

Method of measurement
questionnaire

Secondary outcomes

1

Description
.....

Timepoint
.....

Method of measurement
.....

Intervention groups

1

Description
Magnesium That consist of magnesium oxide (MgO) powder that produced by MERK company and Drug faculty of Isfahan University will make these productions in the shapes of 250 milligram magnesium tablet.the patients will use one tablet daily.

Category
Treatment - Drugs

2

Description

vitamin B6: Magnesium That consist of pyridoxine powder that produced by MERK company and Drug faculty of Isfahan University will make these productions in the shapes of 40 milligram vitamin B6 tablet.the patients will use one tablet daily.

Category

Treatment - Drugs

3

Description

placebo That consist of starch and Drug faculty of Isfahan University will make these productions in the shape of tablet.the patients will use one tablet daily.

Category

Placebo

4

Description

magnesium+vitamin b6 That consist of pyridoxine +magnesium oxide(MgO)powder that produced by MERK company and Drug faculty of Isfahan University will make these productions in the shapes of 40 milligram vitamin B6+250 milligram magnesium tablet.the patients will use one tablet daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical Science health centers

Full name of responsible person

Nahid Fathizadeh

Street address

Isfahan University of Medical, Hezarjarib street, 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

Mariam Kianpour

Street address

Nursing-Midwifery of Isfahan University of Medical Sciences, Hezarjarib street, 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

Isfahan university of medical science

Full name of responsible person

Nahid Fathizadeh

Position

ms.

Other areas of specialty/work

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Full name of responsible person

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Position

ms

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Azad University

Full name of responsible person
Elham Ebrahimi

Position
Ms

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