Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effect of combined use of Calcium and Vitamin B6 on symptoms of premenstrual syndrome

Protocol summary

Summary
This double blind clinical trial performs on 76 students of Hamedan University of Medical Sciences with inclusion criteria: regular menstrual periods with 21-35 days cycles and 3-10 days bleeding period; no known psychological diseases; no physical diseases such as diabetes, seizure disorders, hypothyroidism and so on; no death of close relatives, divorce or other adverse events in the last three months; no Antidepressants, hormonal contraceptives, medroxyprogesterone acetate, and vitamins taken in the past three months and exclusion criteria: pregnancy; incidents like the death of close relatives, divorce, and other adverse events. Subjects take tablets of calcium and vitamin B6 or vitamin B6 two times daily from day 16 of menstrual cycle until day 5 of menstrual cycle. The present study examines the effect of combined use of Calcium and Vitamin B6 on the symptoms of premenstrual syndrome.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2014070313405N3**
Registration date: **2014-11-12, 1393/08/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2014-11-12, 1393/08/21

Registrant information
Name
Seyyedeh Zahra Masoumi
Name of organization / entity
Hamedan University of Medical Sciences, School of Nursing and Midwifery
Country
Iran (Islamic Republic of)
Phone
+98 81 1838 0150
Email address
zahra.masoomi@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice Chancellor of Research of Hamedan University of Medical Sciences

Expected recruitment start date
2014-07-23, 1393/05/01
Expected recruitment end date
2014-11-22, 1393/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of combined use of Calcium and Vitamin B6 on symptoms of premenstrual syndrome

Public title
Effect of Combined Use of Calcium and Vitamin B6 on premenstrual Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: regular menstrual periods with 21-35 days cycles and 3-10 days bleeding period; no known psychological diseases; no physical diseases such as diabetes, seizure disorders, hypothyroidism and so on; no Surgery, death of close relatives; divorce or other adverse events in the last three months; no Antidepressants, hormonal contraceptives, medroxyprogesterone acetate, and vitamins taken in the

past three months; Exclusion criteria: pregnancy; incidents like the death of close relatives; divorce; and other adverse events.

Age
From **20 years** old to **30 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **76**

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
Ethic Committee of Hamedan University of Medical Sciences

Street address
Vice Chancellor of Research and Technology, Hamedan University of Medical Sciences, Shahid Fahmideh Avenue, Hamedan

City
Hamedan

Postal code
6517838695

Approval date
2014-07-21, 1393/04/30

Ethics committee reference number
0097144046691

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
Severity of Premenstrual Syndrome

Timepoint
Eight weeks before treatment, Eight weeks after treatment

Method of measurement
Diagnostic and Statistical Manual of Mental Disorders, 4th. Edition

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Vitamin B6 combined with Calcium tablets, two times a day for two months.

Category
Treatment - Drugs

2

Description
Control group: Vitamin B6 tablet, two times a day for two consecutive months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Ali Ataei

Street address
Vice Chancellor of Research and Technology, Hamedan University of Medical Sciences, Shahid Fahmideh Avenue, Hamedan

City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor of Research of Hamedan University of Medical Sciences

Full name of responsible person
Dr. Saeed Bashiriyan

Street address

Vice Chancellor of Research and Technology, Hamedan University of Medical Sciences, Shahid Fahmideh Avenue, Hamedan

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Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research of Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Seyyedeh Zahra Masoumi

Position

Instructor

Other areas of specialty/work

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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