

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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 Bashiriyani

Street address

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

City

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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**Person responsible for scientific
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Contact

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Full name of responsible person

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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