

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Clinical trial Comparing the effect of relaxation and vitamin B6 on pre-menstrual syndrome in dormitories

Protocol summary

Summary

Comparing the effects of relaxation and vitamin B6 on premenstrual syndrome, this clinical trial study will conduct that aim to compare the effect of relaxation and vitamin B6 on premenstrual syndrome on girls living in dormitory of Rafsanjan University of Medical Sciences. According to the inclusion criteria aged 18 to 25 years; normal menstruation (3 to 8 days of bleeding, and interval between two cycles of 26 to 31 days); no history of use of antidepressants, tranquilizers or hormones, and no crises (loss of dear ones, divorce, ...), 250 girls will select and randomly assign to three groups (vitamin B6 recipients, relaxation trainee and control groups). Relaxation trainee group participate in two training sessions and will ask to do relaxation techniques every day a week before their menstruation. Also, the group receiving vitamin B6 will be asked to start 80 mg vitamin B6 pill three times per week from one week prior to the start of their menstruation. In the control group, there will not be any interference.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070518357N1**

Registration date: **2014-11-24, 1393/09/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-24, 1393/09/03

Registrant information

Name

Nahid Hassani

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 39 1522 3363

Email address

a_ansari@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial Comparing the effect of relaxation and vitamin B6 on pre-menstrual syndrome in dormitories

Public title

Comparing the effect of relaxation and vitamin B6 on pre-menstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 25 to 18 years; Normal menstruation (bleeding interval: 3 to 8 days and during cycle: 26 to 31 days); Single; no history of mental illness and depression; No history of use antidepressants and hormones drug; Did not have any event in past two months

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **250**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, subjects were assigned randomly to one of three groups.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Rafsanjan University of Medical Sciences

Street address

Nursing faculty, Jomhori street, Rafsanjan, Iran

City

Rafsanjan

Postal code

7718796755

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

938

Health conditions studied**1****Description of health condition studied**

Premenstrual Syndrome

ICD-10 code

N.94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes**1****Description**

Premenstrual Syndrome Symptoms

Timepoint

Before the intervention and 3 months after intervention with monthly

Method of measurement

DSM-IV Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

First Intervention group (Relaxation trainee group): received relaxation training in two sessions over one month. These techniques were printed and made available to this group to practice every day, a week before their next menstruation

Category

Treatment - Drugs

2**Description**

Second Intervention group (vitamin B6 recipients): A week before their menstruation, were asked to take 80 mg tablets of vitamin B6 (Iran Hormone Company) 3 times per week, for one month

Category

Treatment - Drugs

3**Description**

The control group: received no intervention.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amin's Residences

Full name of responsible person

Nahid Hassani

Street address

Nursing faculty, Jomhori street, Rafsanjan, Iran

City

Rafsanjan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Rafsanjan University of Medical Sciences

Full name of responsible person
Majid Kazemi

Street address
Nursing faculty, Jomhori street, Rafsanjan, Iran

City
rafsanjan

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 of Rafsanjan 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
Rafsanjan University of Medical Sciences

Full name of responsible person
Dr.Majid Kazemi

Position
Dr

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