

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The Effect of Vitamin B1 on the menstruation's complications Living in a dormitory students

Protocol summary

Summary

The purpose of this controlled random clinical study is to determine the effect of vitamin B1 on the side effects caused by menstoration. This double-blinded clinical trial is performed on 98 unmarried student aged 18 to 26 who that they suffered from level 2 and 3 dysmenorrhea and menstruation cycle duration more than7 days and the number of sanitary napkins used more than 14 had no systemic or reproductive diseases, and who did not use contraceptive drugs between 1395 and 1396. Subjects were randomized into Two groups: Experimental group who received 100 mg vitamin B1pill, its placebo to the control group received. Each participant was monitored during 5 menstrual periods. During the first period participants documented their own Severity of dysmenorrheal and menstruation cycle duration without any intervention applied. During the second, third and forth period, one of the two applications (placebo or vitamin B1pill) was applied . .The samples are evaluated considering the pain and bleeding intensity finally one month later, after finishing intervention (without using drug & placebo).In this study, pain intensity is measured by Multidimensional questionnaires grading scales and menstrual bleeding by Higham chart.

General information

Acronym

Vitamin B1 on the menstruation's complications

IRCT registration information

IRCT registration number: **IRCT2017070710451N2**

Registration date: **2017-07-14, 1396/04/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-14, 1396/04/23

Registrant information

Name

Azam Jafari

Name of organization / entity

Islamic Azad University,Borujerd Branch

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University, Boroujerd Branch

Expected recruitment start date

2016-10-08, 1395/07/17

Expected recruitment end date

2017-10-09, 1396/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Vitamin B1 on the menstruation's complications Living in a dormitory students

Public title

The Effect of Vitamin B1 on the menstruation's complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: unmarried; age18-26; being literate; having regular menstruation period between 26-30 days; Pain a few hours before or at the same time occur with menstrual bleeding; Menstrual pain can take 3 days or

less; menstruations bleeding duration more than 7 days; the number of used sanitary napkins more than 14 numbers; Is not known medical illness; Is not special diet such as weight loss diet, obesity, vegetarian and water treatment; Do not use Tobacco or alcohol; Do not regular exercise. Exclusion criteria: The use of oral contraceptives or other steroid hormones; Existing of any kind of genital system diseases; Background for kidney stone or any problems; any kind of diagnosed physical and psychological diseases.

Age

From **18 years** old to **26 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **98**

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

Islamic Azad University, Arak Branch

Street address

University campus Amir Kabir , Imam Boulevard ,
Imam Squ, Islamic Azad University, Arak Branch

City

Arak

Postal code

38361-1-9131

Approval date

2016-10-08, 1395/07/17

Ethics committee reference number

IR.IAU.ARAK.REC.1395.2

Health conditions studied

1

Description of health condition studied

Pain and other conditions associated with female genital

organs and menstrual cycle Excessive, frequent and irregular menstruation

ICD-10 code

N94.4-N92.

ICD-10 code description

N94.4 Primary dysmenorrhoea N92.0 Excessive and frequent menstruation with regular cycle

Primary outcomes

1

Description

menstrual blood loss

Timepoint

Within 5 months with intervals of 1 month before intervention (at first) , and within 3 months after intervention and 1 month after finishing the intervention.

Method of measurement

Higham chart

2

Description

pain intensity

Timepoint

Within 5 months with intervals of 1 month before intervention (at first) , and within 3 months after intervention and 1 month after finishing the intervention.

Method of measurement

Multidimensional questionnaires grading scales

3

Description

pain duration

Timepoint

Within 5 months with intervals of 1 month before intervention (at first) , and within 3 months after intervention and 1 month after finishing the intervention.

Method of measurement

based on hours

Secondary outcomes

1

Description

spotting

Timepoint

Within 5 months with intervals of 1 month before intervention (at first) , and within 3 months after intervention and 1 month after finishing the intervention.

Method of measurement

Higham chart

Intervention groups

1

Description

100mg edible vitamin B1 pill per day for 3 months

Category

Treatment - Drugs

2**Description**

In control group, edible placebo per day for 3 months

Category

Placebo

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

Student Dormitory

Full name of responsible person

Jafari Azam

Street address

Imam Khomeini university complex, yadegare Imam Ave, Navab Squ, Boroujerd

City

Boroujerd

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

Islamic Azad University, Boroujerd Branch

Full name of responsible person

Dr Mohammad Reza Moazami Goodarzi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University, Boroujerd Branch

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**

Islamic Azad University, Boroujerd Branch

Full name of responsible person

ziba latifiyan

Position

Master of Midwifery, university faculty

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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