

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 2351 8000

##### Email address

a.jafari@iaub.ac.ir

#### 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

**Street address**

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

**City**

Boroujerd

**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

**Other areas of specialty/work****Street address**

Paramedic College, Modares Sq.

**City**

Boroujerd

**Postal code****Phone**

+98 66 4251 3042

**Fax****Email**

zb.latifiyan@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University, Boroujerd Branch

**Full name of responsible person**

Jafari Azam

**Position**

Master of Midwifery, university faculty

**Other areas of specialty/work****Street address**

Paramedic College, Modares Sq.

**City**

Boroujerd

**Postal code****Phone**

+98 66 4251 3042

**Fax****Email**

a.jafari@iaub.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University, Boroujerd Branch

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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*