

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The effect of vitamin B1 on the complications after the insertion of Intra uterin device in women gravid of 1-4

#### Protocol summary

##### Summary

The side effects caused by IUD are the main reasons why women avoid using it continuously. Pain and bleeding are the main side effects of using copper IUD. The purpose of this controlled random clinical study is to determine the effect of vitamin B1 on the side effects caused by IUD insertion. This double-blinded clinical trial is performed on 110 women aged 18 to 35, gravid of 1-4 being applicant for using IUD referring to 4 clinics in the city between 1390 and 1391. After IUD insertion by the midwife of the clinic, the initial questionnaire is completed by the surveyor and then within the first month after IUD insertion, she fills her menstruation characteristics in her check list. If bleeding, menstruation cycle duration, the number of sanitary napkins used, and menstruation pain increase within the first cycle after IUD insertion, she will be chosen as a sample. Then all the selected persons should sign an agreement in order to take part in this experiment. 100 mg vitamin B1 pill is given to the experimental group and its placebo to the control group for 3 months during the second, third and fourth cycle after IUD insertion. The samples are evaluated considering the pain and bleeding intensity within 5 months with intervals of 1 month prior to drug intervention (after IUD insertion), 3 months after drug intervention, and finally one month later, after finishing intervention (without using drug & placebo). In this study, pain intensity is measured by visual analogue scale and menstrual bleeding by Higham chart.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012073010451N1**

Registration date: **2012-12-21, 1391/10/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-12-21, 1391/10/01

##### 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

2012-01-21, 1390/11/01

##### Expected recruitment end date

2012-10-22, 1391/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of vitamin B1 on the complications after the insertion of Intra uterin device in women gravid of 1-4

##### Public title

The effect of vitamin B1 on the complications after the insertion of Intra uterin device

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: : age18-35; Gravid1-4; being literate; using IUD for the first time; having regular menstruation period between 26-30 days; menstruations bleeding duration between 3-7 days;the number of used sanitary napkins between 10-14 numbers.Exclusion criteria:Existing of any kind of genital system diseases ;Background for kidney stone or any problems; any kind of diagnosed physical and psychological diseases; severe dysmenorea, according to visual analogue scale.

## Age

From **18 years** old to **35 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **110**

## 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,Borujerd Branch

##### Street address

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

##### City

Boroujerd

##### Postal code

6915136111

#### Approval date

2012-01-10, 1390/10/20

#### Ethics committee reference number

107901020

## Health conditions studied

### 1

#### Description of health condition studied

Persons encountering health services in circumstances

related to reproduction

## ICD-10 code

z30.1

## ICD-10 code description

Insertion of (intrauterine) contraceptive device

## Primary outcomes

### 1

#### Description

Pain resultant from insertion IUD

#### Timepoint

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

#### Method of measurement

visual analogue scale

### 2

#### Description

bleeding

#### Timepoint

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

#### Method of measurement

Higham chart.

## Secondary outcomes

### 1

#### Description

spotting

#### Timepoint

Within 5 months with intervals of 1 month before intervention, 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**

Shahid kordi health center

**Full name of responsible person**

peidayesh sedighe-Midwife expert

**Street address**

Shahid kordi health center, Qaani St.

**City**

Borujerd

## 2

### Recruitment center

**Name of recruitment center**

Shahid Ragaee health center

**Full name of responsible person**

Ataei Masoume-Midwife expert

**Street address**

Farvardin St. Ayatollah kashani St .

**City**

Boroujerd

## 3

### Recruitment center

**Name of recruitment center**

Besat health center

**Full name of responsible person**

peiryaaee Atefe-Midwife expert

**Street address**

Taleqani St.

**City**

Boroujerd

## 4

### Recruitment center

**Name of recruitment center**

Shahid Beheshti health center

**Full name of responsible person**

Goudarzi Fariba-Midwife expert

**Street address**

Polelavar, Jafari St.

**City**

Boroujerd

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Islamic Azad University,Borujerd Branch

**Full name of responsible person**

Mahdian Mohamad jafar

**Street address**

Imam Khomeini university complex, yadegare Imam Ave, Navab 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,Borujerd 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**

Ministry of Health and Treatment

**Full name of responsible person**

Sayyahi Masoume

**Position**

Master of Midwifery-Employee

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

Health and Treatment center, Navab Sq.

**City**

Boroujerd

**Postal code****Phone**

+66 2 351 3058

**Fax****Email**

SAYYAH1724@GMAIL.COM

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Islamic Azad University,Borujerd 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**

+66 2 350 0201

**Fax****Email**

A.JAFARI@IAUB.AC.IR

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University, Borujerd 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**

+66 2 350 0201

**Fax****Email**

a.jafari@iaub.ac.ir

**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*