

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Jafari Azam

Position

Master of Midwifery,university faculty

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

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Person responsible for updating data

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Name of organization / entity

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Position

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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