Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 continously.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 refering to 4 clinics in the city between 1390 and 1391. After IUD insertion by the midwife of the clinic, the initial guestionnaire 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 B1pill 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 5months 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

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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 .
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3

Recruitment center
Name of recruitment center
Besat health center
Full name of responsible person
peiryaee Atefe-Midwife expert
Street address
Taleqani St.
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4

Recruitment center
Name of recruitment center
Shahid Beheshti health center
Full name of responsible person
Goudarzi Fariba-Midwife expert
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Polelavar, Jafari St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University,Borujerd Branch
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Mahdian Mohamad jafar
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Imam Khomeini university complex, yadegare Imam Ave, Navab Squ, Boroujerd
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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,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
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Person responsible for updating data

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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