Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing of bleeding and dysmenorrhea with Multi Load CU 375 and CU 380A intrauterine device in women referred to health centers in Tabriz:A randomized Clinical Trial.

Protocol summary

Summary

The aim of this randomized controlled trial (double blind) is comparing the bleeding and dysmenorrhea in multi-load 375 and copper T 380 A IUD. We will recruit 48 women 15-45 years old at selected public health center in Tabriz/Iran who have no IUD contraindication and their pain score intensity based on Visual Analoge Scale is below 7 at the time of menstruation. After getting written informed consent, participants will complete demographic characteristics questionnaire and Higham table according to their degree of bleeding and Visual Analog Scale according to pain intensity during menstruation one month before IUD insertion. Then we will randomly allocate them into intervention and control groups using permuted block randomization with block sizes of 4 and 6 concealed in sequentially numbered, sealed, opaque envelopes. IUD insertion immediately after menstrual bleeding will be done. In each menstrual cycle the participants will be asked through phone contact to record the amount of bleeding with Higham table and pain using Visual Analoge Scale during menstruation, in four cycle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109176709N5**
Registration date: **2012-02-01, 1390/11/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-02-01, 1390/11/12

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2012-02-04, 1390/11/15

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of bleeding and dysmenorrhea with Multi Load CU 375 and CU 380A intrauterine device in women referred to health centers in Tabriz:A randomized Clinical Trial.

Public title

Comparing of bleeding and menstrual pain with two types of intrauterine device

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The age range is 15 to 45 years; No

contraindications IUD insertion including: Pregnancy, puerperium sepsis, pelvic inflametory disease or sexually trasmitted infections (currently or in the past 3 months), uterin or cervical cance,unknown genital bleeding, uterin abnormality and fibroid tumors causing deformity in uterus and Wilson's disease; N0 use of hormonal methods of contraception (DMPA in the past one year and OCP, cyclofem in the past 3 months); Delivery time is at least 6 months; score their pain intensity based on Visual Analoge Scale is below 7 at the time of menstruation. Exclusion criteria: Problem in IUD insertion.

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Deputy of Tabriz University of Medical Sciences

Street address
Golgasht St/Tabriz

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Tabriz

Postal code
51665118

Approval date
2012-01-02, 1390/10/12

Ethics committee reference number
9069

Health conditions studied

1

Description of health condition studied
Comparing bleeding and dysmenorrhea with two types of IUD

ICD-10 code
Z30.1

ICD-10 code description
Insertion of (intrauterine) contraceptive device

Primary outcomes

1

Description
Bleeding of IUD insertion

Timepoint
One month before and four months after IUD insertion

Method of measurement
Higham table

Secondary outcomes

1

Description
Dysmenorrhea of IUD insertion

Timepoint
One month before and four months after IUD insertion

Method of measurement
Visual Analoge Scale

Intervention groups

1

Description
Intervention group: Group receiving the multi-load 375 IUD

Category
Prevention

2

Description
Control group: Group receiving the coppr T 380A IUD

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Bavafa health center

Full name of responsible person
Somayyeh Sarrafi Kheirabad

Street address
Monajjem blvd, Tabriz

City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
Golgashat Street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Tabriz University of Medical Sciences
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

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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