Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing Effect Of Mefenamic Acid And Vitex Agnus Castus On IUD-Iinduced Bleeding

Protocol summary

Summary

The aim of this double blind randomized controlled trial is to determine the effect of Mephenamic acid dnd Vitex on copperIUD-induced bleeding and 84 cases of 15-40 years old with copperIUD who have insertion at least 3 monthes ago and with IUD-induced bleeding cpmpliant .Inclusion criterias are: without any drug alergy, atleast 3 monthes past from IUD insertion, IUD - Induced bleeding, without disorders of consumption mefenamic acid (gastrointestinal ulsers ,sensitiveness ,...),atleast education (writing &reading), without any genital infection. Exclusion criteria : any drug disorders after treatment.After getting written informed consent, we will randomly allocate them into intervention and control groups with block sizes of four and six concealed in sequentially numbered identiical containers that are administered serially to participant. Vitex will be used in Mephenamic acid covers .All cases in two groups will be consumpted 3 capeules on day (first day of period untill the end of period)in month for 4 monthes. Amount of bleeding before and after treatmentes will be evaluated for every month and effection of drugs will be compared for 4 monthes . Pads have the samepower on obsorption and made of same factory.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108267418N1**
Registration date: **2012-03-15, 1390/12/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-03-15, 1390/12/25

Registrant information

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Parisa Yavarikia
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing Effect Of Mefenamic Acid And Vitex Agnus Castus On IUD- Iinduced Bleeding

Public title

Effect of Mefenamic Acid And Vitex Agnus Castus On IUD-Induced Bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Without any drug alergy; Atleast 3 monthes past from IUD insertion; IUD - Induced bleeding ; without disorders of consumption mefenamic acidExclusion criteria : Any drug disorders after

intervention

Age
From **15 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

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
Tabriz University Of Medical Sciences - Deputy Of Research

Street address
Tabriz- Golgasht st-Tabriz University Of Medical Sciences-No 2 Building -3 floor -Deputy Of Research

City
Tabriz

Postal code
51665118

Approval date
2011-09-26, 1390/07/04

Ethics committee reference number
5/4/5461

Health conditions studied

1

Description of health condition studied
Uterine Bleeding

ICD-10 code
n93.9

ICD-10 code description
Abnormal Uterine and Vaginal bleeding Unspecified

Primary outcomes

1

Description
months' bleeding

Timepoint
Before and 1and 2 and 3 and 4 monthes after intervention

Method of measurement
Higam table with atleast 100 score

Secondary outcomes

empty

Intervention groups

1

Description
In this study will be used vitex 3 times aday from the first day of period to last bleeding for 4 monthes . it has 1.2-3.3 mg Equin in every meal .Vitex will be used in Mephenamic Acid cover and same as it. Mephnamic Acid will be used 50 mg ,3 times a day for 4 monthes .

Category
Treatment - Drugs

2

Description
In other group will be used Mephenamic acid 500 mg 3 times a day from first day of period until the last period for 4 monthes.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Karag health and treatment centers

Full name of responsible person
Samira Hadavand

Street address
Tabriz south shariati street nursing and midwifery faculty

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University Of Medical Sciences

Full name of responsible person
Dr Rashidi

Street address
Tabriz Daneshgah Street Bleeding 2 floor 5 Deputy of

researches

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Contact

Name of organization / entity

Tabriz University Of Medical Scinces - Nursing And Midwifery Faculty

Full name of responsible person

Samira Hadavand Mirzaie

Position

Master of Midwifery Student

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Web page address

Person responsible for updating data

Contact

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