Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison between the efficacy of Mefenamic acid and Tranxamic acid in control of menorrhagia in IUD users in coverage area of Shahid Beheshti University

Protocol summary

Summary

Objective: To compare the effects of mefenamic acid and tranexamic acid in menorrhagia among IUD users who attending to the health care centers of shahid Beheshti University of medical sciense from April 2012 to December 2013. Design: Single blind prospective clinical trial. Populations: 450 women who attending in urban health care centers of the shahid beheshti University of medical sciense. Inclusion criteria: Patients should be eligible for IUD insertion accordance to state protocol: These patients had regular menstural bleeding before and after IUD insertion:They had long menstrual bleeding more than 7 days and their menstural volume were greater than 80 cc. Exclusion criteria: Patients who had anatomical abnormalities such as uterine myoma and adenomyosis: Coagulopathies: Anticoagulant therapy and genital infection and endometritis and other confounding factors can lead to excesive bleeding. Intervention: The first group take as two 250 mg capsules of Mefenamic Acid three times a day and the second group take 500 mg Tranexamic acid tablets or capsules three times a day. Time of intervention: The intervention took three months for using drugs during hemorrhage. Primary outcome measure: Determine the volume of blood loss,and day numbers , and sequence of bleeding. Secondary outcome measures: Hemoglobin and hematocrit concentration on admission and at the end of the treatment.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015012612494N3**
Registration date: **2015-03-04, 1393/12/13**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-03-04, 1393/12/13

Registrant information

Name

Nasrin Saharkhiz

Name of organization / entity

Infertility & Reproductive Health Research Centre of SHahid Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2558

Email address

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Recruitment status

Recruitment complete

Funding source

Infertility & Reproductive Health Research Centre - Shahid Beheshti of Medical Science

Expected recruitment start date

2012-07-01, 1391/04/11

Expected recruitment end date

2013-11-02, 1392/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the efficacy of Mefenamic acid and Tranxamic acid in control of menorrhagia in IUD users in coverage area of Shahid Beheshti University

Public title
Comparison between two drugs, Mefenamic acid and Tranxamic acid for the treatment of menorrhagia due to IUD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients should be eligible for IUD insertion accordance to state protocol: And after IUD insertion: they have long more than 7 days of menstrual bleeding and menstural volume are greater than 80 cc. Exclusion criteria: Patients with anatomical abnormalities such as uterine myoma and adenomyosis: coagulopathies: anticoagulant therapy and genital infection and endometritis and other confounding factors can lead to increased bleeding.
Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **450**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Infertility & Reproductive Health Research Center Ethics committee of Shahid Beheshti University of
Street address
297 plaque, IVF ward, 3rd floor, Taleghani Hospital, Velenjak, Shahid Chamran highway, Tehran
City
Tehran
Postal code
1985711151
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
308/794

Health conditions studied

1

Description of health condition studied
Excessive, frequent and irregular menstruation
ICD-10 code
N92
ICD-10 code description
Noninflammatory disorders of female genital tract

Primary outcomes

1

Description
Volume of blood loss
Timepoint
Three monthes after start of intervention
Method of measurement
Qulify amount of bleeding on sanitary napkin

2

Description
Number days of bleeding
Timepoint
Three monthes after start of intervention
Method of measurement
Questionare

3

Description
sequence of bleeding.
Timepoint
Three monthes after start of intervention
Method of measurement
Questionare

Secondary outcomes

1

Description
Hemoglobin concentration
Timepoint
Before and three monthes after treatment
Method of measurement
Labratory investigation

2

Description
Hematocrit concentration
Timepoint
Before and three monthes after treatment
Method of measurement
Labratory investigation

Intervention groups

1

Description
Control: The first group take two 250 mg capsule of Mefenamic Acid three times a day.
Category
Treatment - Drugs

2

Description
Intervention: The second group take 500 mg tranexamic acid tablets or capsules three times a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Treatment and health centers of Shahid beheshti university of medical science
Full name of responsible person
Zahra Sadeghzade
Street address
297 plaque, IVF ward,Taleghani hospital, Velenjak, Shahid Chamran highway, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, shahid beheshti University of Medical Sciences
Full name of responsible person
Zahra Sadeghzade
Street address
297 plaque, IVF ward,Taleghani hospital, Velenjak , Shahid Chamran highway, Tehran
City
Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, shahid beheshti 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
Infertility & Reproductive Health Research Center Shahid Beheshti University of Medical Science
Full name of responsible person
Nasrin Saharkhiz
Position
Associate professor of gynecology group
Other areas of specialty/work
Street address
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Person responsible for updating data

Contact

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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