

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 science 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 science. Inclusion criteria: Patients should be eligible for IUD insertion accordance to state protocol: These patients had regular menstrual bleeding before and after IUD insertion: They had long menstrual bleeding more than 7 days and their menstrual 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 excessive 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 menstrual 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 months after start of intervention

Method of measurement

Qulify amount of bleeding on sanitary napkin

2

Description

Number days of bleeding

Timepoint

Three months after start of intervention

Method of measurement

Questionare

3

Description

sequence of bleeding.

Timepoint

Three months after start of intervention

Method of measurement

Questionare

Secondary outcomes

1

Description

Hemoglobin concentration

Timepoint

Before and three months after treatment

Method of measurement

Labratory investigation

2

Description

Hematocrit concentration

Timepoint

Before and three months 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

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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