

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Aug 2026

Evaluation of mizoprostol tablet and mefenamic acid capsule's effect on reducing menstrual bleeding in patients suffering from menorrhagia in Imam Khomeini hospital in 2014.

Protocol summary

Summary

For evaluating the efficacy of misoprostol and mefenamic acid in reducing menorrhagia volume in patients suffering from heavy menstrual bleeding, this double-blinded randomized clinical trial is designed. Patients with subjective complaint of menorrhagia enter the study and they will be excluded if there is any pelvic or systemic pathology present. patients are randomly grouped into two groups. Blood loss volume is assessed in the first menstrual period and during next period, treatment regimen is started. Treatment outcome in next period will be compared with the previous one. Treatment regimens are Mefenamic acid 250 mg capsule three times a day for a group and misoprostol 200 µg three times a day. Treatment goes on for 3 days. The main assessment parameters are blood loss volume which is measured by pictorial blood assessment chart (PBAC) and dysmenorrheal severity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040912790N2**
Registration date: **2014-07-12, 1393/04/21**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-12, 1393/04/21

Registrant information

Name

Tahereh Eftekhari

Name of organization / entity

Valie-Asr Reproductive Health Research Center of

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences - Vice chancellor for research

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-08-22, 1393/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of mizoprostol tablet and mefenamic acid capsule's effect on reducing menstrual bleeding in patients suffering from menorrhagia in Imam Khomeini hospital in 2014.

Public title

Evaluation of mizoprostol tablet and mefenamic acid capsule's effect on reducing menstrual bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

* Inclusion criteria: women with chief complaint of menorrhagia admitted to the clinic * Exclusion criteria: Presence of contraindications to medications Inability to

using medications Presence of ovarian masses or endometrial hyperplasia Presence of systemic disorders such as cardio vascular, hepatic or metabolic diseases.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 40

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

Ethics committee of Tehran University of Medical Sciences

Street address

6th Floor , Tehran University of Medical Sciences, Qods Street , Keshavarz Blvd

City

Tehran

Postal code

Approval date

2012-12-19, 1391/09/29

Ethics committee reference number

91/130 /2357/س

Health conditions studied

1

Description of health condition studied

Menorrhagia

ICD-10 code

N92

ICD-10 code description

Excessive, frequent and irregular menstruation

Primary outcomes

1

Description

Blood loss

Timepoint

First menstruation period - Second Menstruation period

Method of measurement

pictorial blood assesment charts (PBAC)

Secondary outcomes

1

Description

Hemoglobin

Timepoint

First menstrual period - Second menstrual period

Method of measurement

Lab test (gr/dL)

2

Description

dysmenorrhea

Timepoint

First menstrual period - Second menstrual period

Method of measurement

Asking patient (Score 1-10)

3

Description

clot discharge

Timepoint

First menstrual period - Second menstrual period

Method of measurement

Asking patient (Yes/No)

Intervention groups

1

Description

Blood loss is calculated after first menstrual period. Then misoprostol tablet is prescribed for patients so that after second menstrual period, 3 misoprostol 200 µg tablets are used for 3 days. PBAC is used for assessing amount of blood loss.

Category

Treatment - Drugs

2

Description

Blood loss is calculated after first menstrual period. Then mefenamic acid capsule is prescribed for patients so that after second menstrual period, 3 mefenamic acid 250mg capsules are used for 3 days. PBAC is used for assessing amount of blood loss.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-E-Asr hospital

Full name of responsible person

Dr.Tahereh Eftekhari

Street address

Gynecology clinic - Vali-e-asr hospital - Imam
Khomeini hospital complex - Keshavarz Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences - Vice
chancellor for research

Full name of responsible person

Dr. Masoud Younesian

Street address

6th Floor - Tehran University of Medical Sciences -
Qods Street - Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences - Vice chancellor
for research

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

Tehran University of Medical Sciences

Full name of responsible person

Dr.Aref Abedi

Position

Medical Doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Gynecology Specialist

Other areas of specialty/work

Street address

Gynecology ward - Vali-e-asr hospital - Imam
Khomeini hospital complex - Keshavarz Blvd - Tehran
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Person responsible for updating data

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Name of organization / entity

Tehran University of Medical Sciences

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Dr.Aref Abedi

Position

Medical Doctor

Other areas of specialty/work

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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