Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Eftekhar

Name of organization / entity

Valie-Asr Repductive Health Research Center of Tehran University of Medical Sciences

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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/د

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 Eftekhar

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

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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

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

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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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Gynecology Specialist

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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