

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effects of Tranexamic acid and Mefenamic acid in treating menorrhagia

Protocol summary

Summary

Aim: This study compares the efficacy and acceptability of Tranexamic acid with Mefenamic acid in treating menorrhagia in order to show the most effective, and at the same time, the most acceptable drug for Iranians.

Design: Single blind clinical trial. **Method:** During 2011-2012, 60 patients, aged 15-49, with menorrhagia who referred to Ayatollah Taleghani hospital in Tehran, Iran, were randomly divided into 2 thirty-patient groups. The first group received Mefenamic acid cap and the other received Tranexamic acid cap during the first three days of their period for 2 subsequent cycles; following that their bleeding changes were evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011912190N1**

Registration date: **2013-02-23, 1391/12/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-23, 1391/12/05

Registrant information

Name

Shiva Hadadian

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 23871

Email address

shivahadadian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2011-02-09, 1389/11/20

Expected recruitment end date

2012-03-15, 1390/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Tranexamic acid and Mefenamic acid in treating menorrhagia

Public title

Comparing the effects of Tranexamic acid and Mefenamic acid in treating heavy menstrual bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women aged 15-49 suffering from heavy menstrual bleeding or long menstrual duration.

Exclusion criteria: organic causes were excluded by history, physical exam, lab test.

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

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
Shahid Beheshti University of Medical Sciences
Street address
Arabi st., Yaman st., Chamran Highway
City
Tehran
Postal code
Approval date
2012-12-23, 1391/10/03
Ethics committee reference number
128

Health conditions studied

1

Description of health condition studied
menorrhagia
ICD-10 code
N80-N98
ICD-10 code description
Noninflammatory disorders of female genital tract

Primary outcomes

1

Description
Menstrual duration
Timepoint
one month before treatment,two subsequent month
during treatment and one month following treatment
Method of measurement
questionnaire

2

Description
Menstrual bleeding volume
Timepoint
one month before treatment,two subsequent month
during treatment and one month following treatment

Method of measurement

Pictorial chart on which patients marked the type and the number of pads theyused during menstrual bleeding..

Secondary outcomes

1

Description
complication ,like vertigo, dyspepsia,epigasteric
pain,thrombosis
Timepoint
one month following treatment
Method of measurement
questionnaire

2

Description
choosing the drug if the problem recur
Timepoint
one month following treatment
Method of measurement
questionnaire

3

Description
patient satisfaction with the treatment
Timepoint
one month following treatment
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group:Tranexamic acid capsule 250 mg
,oral, every 8 hour in the first 3 days of bleeding on two
subsequent cycles
Category
Treatment - Drugs

2

Description
Control group:Mefenamic acid capsule 250 mg
,oral,every 8 hour in the first 3 days of bleeding on two
subsequent cycles
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gynecology Clinic of Taleghani hospital
Full name of responsible person

Dr. Shiva Hadadian, Obstetric and Gynecology
Resident (student)

Street address

Next to Shahid Beheshti University of Medical
Sciences, Evin

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Taleghani Hospital of Tehran

Full name of responsible person

Dr. Shiva Hadadian

Street address

Next to Shahid Beheshti University of Sciences, Evin

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Taleghani Hospital of Tehran

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

Taleghani Hospital of Tehran

Full name of responsible person

Shiva Hadadian

Position

Obstetric and Gynecology Student (Resident)

Other areas of specialty/work

Street address

Shahid Beheshti University of Medical Sciences, Evin

City

Tehran

Postal code

Phone

+98 21 2243 2560

Fax

+98 21 2243 2570

Email

taleghanihospital@sbmu.ac.ir

Web page address

www.taleghanihospital.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Sciences

Full name of responsible person

Dr. Shiva Hadadian

Position

Obstetric and Gynecology Student (resident)

Other areas of specialty/work

Street address

Velenjak, Shahid Chamran highway

City

Tehran

Postal code

Phone

+98 21 2241 4131

Fax

+98 21 2240 3154

Email

info@sbmu.ac.ir

Web page address

www.sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Taleghani Hospital of Tehran

Full name of responsible person

Dr. Shiva Hadadian

Position

Obstetric and Gynecology Student (resident)

Other areas of specialty/work

Street address

Next to Shahid Beheshti University of Sciences, Evin

City

Tehran

Postal code

Phone

+98 21 2243 2560

Fax

+98 21 2243 2570

Email

taleghanihospital@sbmu.ac.ir

Web page address

www.taleghanihospital.ir

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