

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effect of mefenamic acid and naproxen on the amount of heavy menstrual bleeding in women of reproductive age: a placebo-controlled study.

Protocol summary

Summary

The aim of this study is to compare the efficacy of mefenamic acid and naproxen in the reduction of heavy menstrual bleeding. Women of reproductive age, who suffer from heavy menstrual bleeding, will be recruited in this randomized placebo-controlled study. Participants, who meet inclusion criteria, will be evaluated for 6 menstrual cycles. During the first 3 control cycles, they will record the amount of bleeding on Pictorial Blood Assessment Chart to confirm their having heavy menstrual bleeding. Then, 120 participants, who consent to receive interventions, will be randomly assigned to receive mefenamic acid, naproxen or placebo. Each group will take tablets four times daily from day 1 to 7 of menstrual cycle. All participants will fill in the Pictorial Blood Assessment Chart during the three intervention cycles. After the 3 intervention cycles the charts will be collected and the effect of each medication on the amount of bleeding will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204241548N14**

Registration date: **2012-05-05, 1391/02/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-05-05, 1391/02/16

Registrant information

Name

Khadijeh Abdali

Name of organization / entity

Fatemeh college of nursing and midwifery, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4255

Email address

abdalikh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy for Research of Shiraz University of Medical Sciences

Expected recruitment start date

2012-06-01, 1391/03/12

Expected recruitment end date

2012-12-30, 1391/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mefenamic acid and naproxen on the amount of heavy menstrual bleeding in women of reproductive age: a placebo-controlled study.

Public title

The effect of mefenamic acid, naproxen and placebo on periodic bleeding in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were the followings: a) being between 20 and 45 years old of age; b) normal results for cervical smear test; c) negative history of renal or hepatic

impairment, thromboembolic disease, inflammatory bowel disease, peptic or intestinal ulceration, coagulation or fibrinolytic disorders; d) normal results for blood tests (including PT, PTT, BT, TSH); e) not taking any hormones and NSAIDs. Exclusion criteria included: a) infertility; b) overweight/obesity (BMI>25) or underweight (BMI<18.5); c) polycystic ovaries; d) vaginitis and/or pelvic inflammatory disease (PID); e) uterine polyps and/or fibroids; f) carrying IUD; g) being perimenopausal (increased serum FSH showed being premenopausal).

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical Research Ethics Committee of Shiraz
University of Medical Sciences

Street address

Zand St,

City

Shiraz,

Postal code**Approval date**

2009-02-20, 1387/12/02

Ethics committee reference number

87-3666

Health conditions studied**1****Description of health condition studied**

Heavy menstrual bleeding

ICD-10 code

N92.1

ICD-10 code description

Excessive and frequent menstruation with irregular cycle

Primary outcomes**1****Description**

Amount of menstrual bleeding

Timepoint

One month

Method of measurement

Pictorial Blood Assessment Chart

Secondary outcomes**1****Description**

Decrease in the amount of menstrual bleeding

Timepoint

one month

Method of measurement

Pictorial Blood Assessment Chart

Intervention groups**1****Description**

Participants in the first group will receive tablets containing 250 mg of mefenamic acid four times daily (1000 mg total daily intake) from day 1 to day 7 of each menstrual cycle.

Category

Treatment - Drugs

2**Description**

Participants in the second group will receive tablets containing 250 mg of naproxen four times daily (1000 mg total daily intake) from day 1 to day 7 of each menstrual cycle.

Category

Treatment - Drugs

3**Description**

Participants in the third group will receive placebo tablets four times daily from day 1 to day 7 of each menstrual cycle.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeynabiyeh Hospita,

Full name of responsible person

Street address

City

Shiraz,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy for Research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Mohammad Hosein Dabbagh Manesh

Street address

Zand St,

City

Shiraz,

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy for Research of Shiraz 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

Fatemeh College of Nursing and Midwifery, Shiraz University of Medical Sciences

Full name of responsible person

Khadijeh Abdali

Position

Master's Degree in Midwifery, Faculty Member

Other areas of specialty/work

Street address

Namazi Square,

City

Shiraz,

Postal code

Phone

+98 71164742528

Fax

Email

abdalikh@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Fatemeh College of Nursing and Midwifery, Shiraz University of Medical Sciences

Full name of responsible person

Khadijeh Abdali

Position

Master's Degree in Midwifery, Faculty Member

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Street address

Namazi Square,

City

Shiraz,

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+98 71164742528

Fax

Email

abdalikh@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Khadijeh Abdali

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

Web page address

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