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 reprodcutive 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)

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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 reprodcutive 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Khadijeh Abdali
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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