Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of oral consumption extract hydrophilia of pomegranate peel and Mefenamic Acid on menorrahagia disease

Protocol summary

Summary

The present study is randomized and double blinded. The purpose of this study is to compare the effects of the hydrophilic extract of pomegranate peel and Mefenamic acid capsules in the treatment of menstrual menorrhagia in patients who referred to Mostafa Khomeini Hospital, Shahed Healthcare and the co-worker Gynecologist Clinic. The study population includes 60 women with menorrhagia who referred to these treatment centers. The study includes women aged 20 to 50 who are not pregnant; and do not have a plan on pregnancy in the next three months; and do not have pathologic causes; or systemic diseases which bring about blood disorders like diabetes; coagulation disorders; hypothyroidism; hyperthyroidism; liver problems; and menstrual disorders. At first, the patients fill out the midwifery, Demographic and menorrhagic questionnaires, and the PBAC charts. Then they are divided into two therapeutic groups. Members of group A take 250 mg capsules of Mefenamic acid every eight hours from day one to seventh of menstruation. Group B takes capsules containing hydrophilic extract of pomegranate peel every eight hours from the first day of menstruation till the seventh. During the treatment the patients fill out the PBAC chart and the drug use questionnaire. Then a survey of satisfaction and acceptance of treatment is conducted and the effects of the drugs are compared and contrasted with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090936103N1**
Registration date: **2017-11-18, 1396/08/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-11-18, 1396/08/27

Registrant information

Name
Gholamreza Salsali
Name of organization / entity
Shahed University
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Iran (Islamic Republic of)
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+98 21 5121 3553
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Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral consumption extract hydrophilia of pomegranate peel and Mefenamic Acid on menorrahagia disease

Public title

Comparison of oral consumption of pomegranate peel and Mefenamic Acid on Efrat tams disease

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients with high or long uterine bleeding who have had a negative pregnancy test; and are not breast-feeding; in ultrasonography their thickness of endometrium is normal; there is no mass of adnexa and ovaries except for a simple cyst less than two centimeters; genecology examination and Pap smear tests are normal; they’re not taking other hormonal and anticoagulant drugs like aspirin; or herbal drugs and teas; they do not have systemic or organic diseases and bleeding disorders; In the ultrasound the size of the uterus is less than 10 cm; there is no submucosal or intramural fibroma; and sub-serous fibroma is not bigger than 4 cm; they do not use IUD; and do not have BMI greater than 30; CBC and Hb are not less than 10. Exclusion criteria: Taking hormonal drugs during the study; experiencing possible side effects like anemia (Hb less than 10); needing surgery or other interventions; leaving the study on personal requests; requiring emergency procedures during the study due to severe bleeding; occurrence of pregnancy; and experiencing serious side effects due to the drugs.

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

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 Shahed University

Street address
Shahed University, in front of the shrine Imam Khomeini (RA), Persian Gulf Highway

City
Tehran

Postal code
3319118651

Approval date
2017-10-30, 1396/08/08

Ethics committee reference number
IR.Shahed.REC.1396.60

Health conditions studied

1

Description of health condition studied
Menorrhagia

ICD-10 code
N92.0

ICD-10 code description
excessive and frequent menstruation with regular cycle

Primary outcomes

1

Description
bleeding Volume

Timepoint
One month before, first, second and third month after intervention

Method of measurement
Pictorial Blood Loss Assessment Chart

2

Description
bleeding Volume

Timepoint
One month before, first, second and third month after intervention

Method of measurement
Pictorial Blood Loss Assessment Chart

Secondary outcomes

1

Description
Hb level

Timepoint
Before and 3 months after intervention

Method of measurement
Lab test

2

Description
Quality of life

Timepoint
Before and 3 months after intervention

Method of measurement
Menorrhagia questionnaire

Intervention groups

1

Description
Intervention 1. A 250 mg capsule extract of pomegranate peel is consumed after each meal in 7 days of menstruation for three cycles.
Category
Treatment - Drugs

2

Description
Intervention 1. A 250 mg capsule of Mefenamic Acid is consumed after each meal in 7 days of menstruation for three cycles.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mostafa Khomeini Hospital
Full name of responsible person
Gholamreza Salasli
Street address
Tehran Province, Tehran, Palestine Street, Italy St
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Zahra Kiasalari
Street address
Shahed University, in front of the shrine Imam Khomeini (RA), Persian Gulf Highway
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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
Shahed University
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
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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