

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Clinical trial of comparing the effect of hydro alcoholic extract of Capsella Bursa Pastoris capsules and Mefenamic acid on the amount and duration of menstrual bleeding in women affected by menorrhagia

Protocol summary

Summary

Menorrhagia is one of the most common gynecological problems and one of the causes of poor quality of life and iron deficiency anemia in women of reproductive age. As there is no research on the effect of Capsella Bursa-Pastoris on menorrhagia, this study is conducted to determine the effect of hydroalcoholic extract of Capsella Bursa-Pastoris on menorrhagia. In this clinical trial, 90 women with complaint of menorrhagia were selected and after a control cycle for evaluating the primary bleeding volume, using Exel software, were randomly allocated to capsella bursa pastoris or control groups. Inclusion criteria: Body mass index between 18.5-29.9, Affected by menorrhagia, Age between 18-45 years. No history of known systemic or pelvic inflammatory diseases, Not pregnant, Not consumption of specific medications, No abnormal pap smear or ultrasonography, No history of sensitivity to medicinal plants. Exclusion criteria: sensitivity to the study medications, Failure to adhere to prescribed treatment, Unwilling to continue participation in the study, Tacking any herbal or chemical drug during the study. Both groups were subjected to mefenamic acid capsule with 500 mg every 8 hours, from the first day to the end of bleeding, up to seven days, for two consecutive cycles. In capsella bursa pastoris group, in addition to mefenamic acid, capsella bursa pastoris capsules, two capsules every 12 hours per day, from the first day to the end of bleeding, up to seven days, were prescribed. In control group, instead of capsella bursa pastoris capsules, placebo of capsella bursa pastoris was prescribed with the same order. Data on the amount and duration of bleeding (using Higgam chart) were checked and compared before and after treatment using SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410034529N13**

Registration date: **2014-12-10, 1393/09/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-10, 1393/09/19

Registrant information

Name

Nourossadat Kariman

Name of organization / entity

Shaheed Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8888 3133

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparing the effect of hydro alcoholic extract of Capsella Bursa Pastoris capsules and Mefenamic acid on the amount and duration of menstrual bleeding in women affected by menorrhagia

Public title

Effect of Capsella Bursa Pastoris on heavy menstrual bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Regular menstrual cycles, Body mass index between 18.5- 29.5, Affected by menorrhagia, Age between 18-45 years, No history of known systemic or pelvic inflammatory diseases, Not pregnant, Not consumption of specific medications, No abnormal pap smear or ultrasonography, No history of sensitivity to medicinal plants. Exclusion criteria: sensitivity to the study medications, Pregnancy during the study, Failure to adhere to prescribed treatment, Unwilling to continue participation in the study, Occurrence of a specific disease, Taking any herbal or chemical drug during the study, Occurrence of a specific event during the study.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

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

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

This study has been done by triple blind method. To do this, patients, researcher and statistical consultant were not aware of prescribed drug's nature. 90 women using Excel software, were randomly allocated to capsella bursa pastoris or control groups.

Secondary Ids

empty

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

Ethics committee of Shahid Beheshti of University of Medical Sciences

Street address

Beside Taleghani hospital, Shahid Arabi St., Yaman St., Shahid Chamran Highway, Tehran

City

Tehran

Postal code**Approval date**

2013-12-01, 1392/09/10

Ethics committee reference number

143

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**

Amount of bleeding

Timepoint

before treatment, First month during treatment, second month during treatment

Method of measurement

Higam Chart

2**Description**

Duration of bleeding

Timepoint

before treatment, First month during treatment, second month during treatment

Method of measurement

Higam Chart

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

Side effects of medication

Timepoint

2 months after treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention 1: In Capsella Bursa Pastoris group, Mefenamic acid capsules, 500 mg every 8 hours and hydro alcoholic extract of Capsella Bursa Pastoris capsules, 500 mg per day, every 12 hours, were prescribed, from the first day to the end of bleeding up to seven days.

Category

Treatment - Drugs

2

Description

Intervention 2: In control group, Mefenamic acid capsule 500 mg every 8 hours and placebo capsules 500 mg per day, every 12 hours, were prescribed from the first day to the end of bleeding up to seven days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Street address

Shahrdary St., Ghods Sq., Tajrish, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Beside Taleghani Hospital, Shahid Arabi St., Yaman St., Shahid Chamran Highway, Tehran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Shahid Beheshti 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

School of Nursing and Midwifery Of Shahid Beheshti

Full name of responsible person

Noora Kariman

Position

Reproductive Health phd

Other areas of specialty/work

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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