Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 sevsn 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 Higam 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)

Phone

+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 between18.5- 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 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
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Beside Taleghani Hospital, Shahid Arabi St., Yaman St., Shahid Chamran Highway، Tehran
City
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
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Person responsible for updating data

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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