Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Capsella bursa-pastoris with placebo in Menometrorrhagia and quality of life in patients with uterine leiomyoma.

Protocol summary

Study aim

Determination of the effect of Capsella bursa-pastoris on the amount and duration of uterine bleeding in patients with uterine leiomyoma.

Design

This study is double-blind, placebo-controlled, randomized clinical trial with a parallel group design of 47 patients which are randomized with block method.

Settings and conduct

The site of this study is the Persian Medicine Clinic and the Women's Clinic of Foroghani Hospital in Qom. In this double-blind study, the patient and the investigator will not be aware of the nature of prescribing drugs. Patients during 3 consecutive cycles, take the medication every day and fill up Pictorial blood assessment chart. At the end, the amount of bleeding, the duration of menstruation and the number of the used pads and also quality of life for both groups have been investigated before and after treatment, and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women 18 to 50 years old with menometrorrhagia and uterine leiomyoma without systemic disease; Non-use of any effective medication on menstrual bleeding; Non-use of hormone, anti-fibrinolytic or systemic glucocorticoid; Non-use of Monoamine oxidase inhibitors, Non-use of herbal remedy during the 2 weeks before the study; Having no abnormal pap smear; no pregnancy; no breast feeding. Exclusion criteria: incidence of surgical indications; unwilling to continue participation in the study; incidence of side-effects requiring special treatment.

Intervention groups

The intervention group is treated with 500 mg capsules containing a Capsella bursa-pastoris extract and starch, twice a day. The control group will receive 500 mg of capsules containing starch, twice a day.

Main outcome variables

Menstrual bleeding, Menstrual bleeding days, Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161226031582N1**
Registration date: **2018-01-11, 1396/10/21**
Registration timing: **prospective**

Last update: **2019-05-12, 1398/02/22**
Update count: **1**

Registration date

2018-01-11, 1396/10/21

Registrant information

Name

Atieh sadat Danesh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

2018-02-05, 1396/11/16

Actual recruitment end date

2019-01-21, 1397/11/01

Trial completion date

2019-04-27, 1398/02/07

Scientific title

Comparison of Capsella bursa-pastoris with placebo in Menometrorrhagia and quality of life in patients with uterine leiomyoma.

Public title
Effect of Capsella bursa-pastoris with placebo on abnormal uterine bleeding and quality of life in patients with uterine leiomyoma.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having a score more than 100 in Pictorial blood assessment chart Age between 18 to 50 years old The existence of uterine leiomyoma proven in ultrasound No use of any effective medication on menstrual bleeding such as: 0CP, ASA, anti-coagulant No regular use of special herbal remedy during the 2 weeks before the study No systemic disease such as :Thyroid, Hyperprolactinemia, Coagulopathy, hemoglobinopathy No abnormal pap smear No pregnancy No breast feeding

Exclusion criteria:
Incidence of surgical indications such as: abnormal bleeding disorder of vital signs, resistant anemia to usual treatments, severe anemia (hemoglobin below 7), acute pain, severe urinary symptoms or hydronephrosis The use of any hormone, anti-fibrinolytic or systemic glucocorticoid The use of Monoamine oxidase inhibitors allergy to the drug studied Pregnancy during the study Unwilling to continue participation in the study Incidence of side-effects requiring special treatment

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **120**
Actual sample size reached: **47**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation of patients to the two groups is based on the block method. The size of block 4 is considered. So there are six quadruple blocks, including AABB, ABAB, BBAA, BABA, ABBA, BAAB. Selection of each block will also be a crash and will be done using dice throwing. According to the sample size of 120 and the fourth block, at least 30 blocks are required.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted double-blinded.For this purpose, patients and the investigator will not be aware of the nature of prescribing drugs. For this purpose, each participant is given code at the beginning of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Biomedical Research of Qom University of Medical Sciences

Street address
Plaque 83, 4th Alley, 1/1 Lane, Safashar Street

City
Qom

Province
Ghoum

Postal code
87366-37169

Approval date
2017-10-31, 1396/08/09

Ethics committee reference number
IR.MUQ.QEC.1396.110

Health conditions studied

1

Description of health condition studied
Menometrorrhagia

ICD-10 code
N92.0

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

Primary outcomes

1

Description
Amount of Menstrual bleeding

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

Method of measurement
Higam Chart

2

Description
Duration of Menstrual bleeding

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

Method of measurement
Calendar

3

Description
Quality of life
Timepoint
Before and 3 months after intervention
Method of measurement
Menorrhagia questionnaire

Secondary outcomes

1

Description
size of uterine leiomyoma
Timepoint
Before and 3 months after intervention
Method of measurement
Ultrasound

2

Description
Side effects of medication
Timepoint
3 months after intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Treated with 500mg capsules containing Capsella bursa-pastoris extract and starch, they will be placed three times a day between meals at 10am, 5am and will sleep for three months before bedtime.
Category
Treatment - Drugs

2

Description
Control group:The control group will receive 500 mg ofcapsules containing starch, three times a day between meals at 10:00 am, 5 am and before bedtime for three months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Zafar clinic
Full name of responsible person
Atiehsadat Danesh
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Dr Hossein Saghafi
Street address
No. 83,Alley 1/1, Alley 4,Safashahr Street,Deputy of Research of Qom University of Medical Sciences
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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
Ghoum University of Medical Sciences
Proportion provided by this source

100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Atiehsadat Danesh

Position
consultant

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Deidentified Individual Participant Data Set: primary and secondary outcome measure only, study Protocol, informed consent form, clinical study report.

When the data will become available and for how long
Start the access period 6 months after printing the results.

To whom data/document is available
For researchers working in academic and scientific institutions.

Under which criteria data/document could be used
For academic use and sent by academic mail.

From where data/document is obtainable
Contact me by email.

What processes are involved for a request to access data/document

To the request sent to me by academic mail,the documentation will be emailed as soon as possible.

Comments