

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effectiveness of suppository plantago leaf extract on quantity of menstrual bleeding in patients with uterine leiomyoma

Protocol summary

Study aim

The effect of plantago major suppository on the volume of menstrual bleeding in patients with uterine leiomyoma

Design

A randomized clinical trial study was conducted in a control group with parallel and bilingual blind groups. The sample size was 60. They were divided into two groups A and B, using the Randomization Block method, which were divided into Group A is given a drug and Group B is given a placebo.

Settings and conduct

In this method a group of patients Mefenamic acid capsule every 8 hours, one_ hour plus vaginal suppository, every 8 hours, one day and another group of mefenamic acid, every 8 hours one day plus placebo suppository, every 8 hours, one vaginal number in the first three days of menstruation that have a large amounts of bleeding, receives them. Research location: Obstetrics and Gynecology, Supra clinic touba, Sari City.

Participants/Inclusion and exclusion criteria

-Inclusion criteria: -Being 18 to 50 years old -Having ultrasonography of submucosal uterine leiomyoma with uterine bleeding
Exclusion criteria: - Women with Surgical indication -Fast increase in mass size after menopause - positive pregnancy test -Known severe coagulation disease -Hb under 9/5

Intervention groups

Intervention group: Vaginal suppositories of plantago leaf extract is prescribed in the first three days of menstruation in two consecutive months
Control group: All the components of the intervention group suppository except plantago leaf extract

Main outcome variables

Blood volume

General information

Reason for update

Acronym

اثر بارهنگ بر خونریزی قاعدگی

IRCT registration information

IRCT registration number: **IRCT20181001041191N1**

Registration date: **2019-02-22, 1397/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-22, 1397/12/03**

Update count: **0**

Registration date

2019-02-22, 1397/12/03

Registrant information

Name

fatemeh navaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of suppository plantago leaf extract on quantity of menstrual bleeding in patients with uterine leiomyoma

Public title

Effect of plantago major in menstrual bleeding in patients with uterine leiomyoma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having an age 18- 50 BMI 18/5- 29/9 Regular menstrual cycle Being married submucosal leiomyoma in ultrasonography with menstrual bleeding Unwillingness Or contraindication to taking hormone

Exclusion criteria:

Surgical indication Unusual bleeding Anemia resistant to usual treatments Dysmenorrhea or severe dyspnea Acute pain Symptoms of severe urination or hydronephrosis Fast increase in mass size Start of tumor growth after menopause Patients with gastrointestinal complications Patients treated with progesterone Patients treated with acetylsalicylic acid Patient treated with anti - coagulan Patient treated with tranexamic Acid AND Ocp Taking miphe priston ' aganists NSAID' Gnrh Woman have positive pregnancy test Known hemoglobinopathy Known severe coagulation disease anti-fibrinolytic or systemic glucocorticoids Hb under 9/5 Pap smear due to displasticity disorders Having IUD

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients referring to women's clinic that are based on examinations criteria They will be admitted to the study and the diagnosis of their uterine leiomyoma will be included in the study. 60 samples will be assigned by blocking method to two groups. The sample allocation method will be performed using the software, and the samples will be assigned in four blocks, Random numbers are for blocks through the software. Patients will be placed in two groups A and B using the Randomization Block. Group A is given drug and given to Group B placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

For double - blind blinding, medications are prepared in special envelopes with the installation of two - digit codes until the final evaluator who is a gynecologist is not aware of the type of medication received. also, for lack of information to the patient The drug received by preparing a placebo in Sari Pharmacy School that It looks

be looks like a plantago major suppository that for the control group will be considered and the patients will not be aware of the type of drug they receive.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Teacher Street, Teacher's Square

City

Sari

Province

Mazandaran

Postal code

48168-95474

Approval date

2018-07-03, 1397/04/12

Ethics committee reference number

IR.MAZUMS.REC.1397.157

Health conditions studied**1****Description of health condition studied**

Submucous leiomyoma of uterus

ICD-10 code

D25.0

ICD-10 code description

Submucous leiomyoma of uterus

Primary outcomes**1****Description**

volume of bleeding menstruation

Timepoint

The first three days of menstruation in two consecutive months

Method of measurement

Standard Bleeding Reporting Form PBAC

Secondary outcomes

1

Description

Blood volum

Timepoint

The first three days of the menstrual cycle

Method of measurement

PBAC questionnaire

Intervention groups

1

Description

Intervention group: A total of 30 patients were treated with vaginal suppository of plantago leaf extract in two consecutive months during the first three days of menstruation

Category

Treatment - Drugs

2

Description

Control group: 30 patients with hemorrhagic fibroma receiving the suppository containing all the components of the intervention group formulation, except for plantago leaf extract.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Touba clinic

Full name of responsible person

Syedeh Sedigheh Yousefi

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Sponsors / Funding sources

1

Sponsor

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Syedeh Sedigheh Yousefi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Resident

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available