Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of suppository plantago leaf extract on quantity of menstural 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 lyomium

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 placeb.

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 lyomium with uterine bleeding Exite 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

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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 menstural 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 Unusal 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 blonding, medications are prepared in special envelops 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
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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

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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
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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