Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the combined effect of black cohosh and misoprostol on the rippening cervix prior to hysteroscopy in postmenopausal women

Protocol summary

Study aim
Evaluation of the effect of black cohosh root with misoprostol on cervical preparation before hysteroscopy in postmenopausal women

Design
A randomized controlled clinical trial with parallel, double-blind, randomized groups.

Settings and conduct
66 patients were included in the study and randomly divided into two groups of 33 people. In all patients before and after the operation, the pain level is measured based on the VAS scale. The first group takes 200 micrograms of misoprostol 6-8 hours before the operation. And the second group will receive 80 mg of black cohosh in addition to 200 micrograms of misoprostol 6-8 hours before the operation.

Participants/Inclusion and exclusion criteria
Post-menopausal women who, according to the definition, have passed their last period for more than 1 year and are candidates for elective hysteroscopy due to post-menopausal bleeding (polyp, myoma or endometrial thickening).

Intervention groups
The first group takes 200 micrograms of misoprostol 6-8 hours before the operation. And the second group will receive 80 mg of black cohosh in addition to 200 micrograms of misoprostol 6-8 hours before the operation.

Main outcome variables
cervix rippening

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230318057754N1**
Registration date: **2024-01-24, 1402/11/04**
Registration timing: **prospective**

Last update: **2024-01-24, 1402/11/04**
Update count: **0**

Registration date
2024-01-24, 1402/11/04

Registrant information

Name
Athena Behforouz

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2220 3664

Email address
behforouz.a@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-10, 1402/12/20

Expected recruitment end date
2024-07-20, 1403/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the combined effect of black cohosh and misoprostol on the rippening cervix prior to hysteroscopy in postmenopausal women

Public title

Comparative study of the combined effect of black cohosh and misoprostol on the rippening cervix prior to hysteroscopy in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Post-menopausal women who, according to the definition, have passed their last period for more than 1 year and are candidates for elective hysteroscopy due to post-menopausal bleeding (polyp, myoma or endometrial thickening).

Exclusion criteria:

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block, we divide 4 people into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti University of Medical Sciences

Street address

Tehran Province, Tajrish، Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-12-26, 1402/10/05

Ethics committee reference number

IR.SBMU.MSP.REC.1402.488

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

E35

ICD-10 code description

Disorders of endocrine glands in diseases classified elsewhere

Primary outcomes

1

Description

cervix rippening

Timepoint

Before and after surgery

Method of measurement

Patient response based on Visual Analogue Scale (VAS) score

2

Description

Complications of hysteroscopy including bleeding and pain

Timepoint

Before and after surgery

Method of measurement

Patient response based on Visual Analogue Scale (VAS) score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 6-8 hours before the operation, in addition to 200 micrograms of misoprostol (Samisaz Pharmaceutical Company), they will receive 80 mg of black cohosh (Faculty of Traditional Medicine, Shahid Beheshti University of Medical Sciences). Medicines are used vaginally and a single dose is used.
Category
Treatment - Drugs

2

Description
Control group: take 200 micrograms of misoprostol (Samisaz Pharmaceutical Company) 6-8 hours before surgery. Medicines are used vaginally and one dose is used.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdiye hospital
Full name of responsible person
Atena Behrorouz
Street address
Tehran, Shush Square, Shahrzad Avenue, Mahdieh Hospital
City
Tehran
Province
Tehran
Postal code
1185817311
Phone
+98 21 5506 2628
Email
shoku70@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Abbas Motavalian
Street address
Shahid Beheshti University of Medical Sciences, Koodakyar Ave, Daneshju Blvd, Velenjak, Tehran, IRAN
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
dean.medicalschool@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Athena Behforouz
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Tehran Province, Tajrish، Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
dean.medicalschool@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Athena Behforouz

Position
Associate professor
Latest degree
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Other areas of specialty/work
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City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
dean.medicalschool@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Athena Behforouz
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Tehran Province, Tajrish، Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
dean.medicalschool@sbmu.ac.ir

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
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All individual data of the participants in this study will be shared after unidentifiable individuals
When the data will become available and for how long
The access period will start from 2022to 2023
To whom data/document is available
Data will be available to researchers working in the university.
Under which criteria data/document could be used
Just for performing research
From where data/document is obtainable
Refer to the responsible person for accessing the data
What processes are involved for a request to access data/document
The data will be available one month after the responsible person's approval
Comments