Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Effectiveness of Oral and Vaginal Misoprostol Administration for Cervical Ripening in Women Before Operative Hysteroscopy: A Double-Blind Randomized Placebo Controlled Clinical Trial

Protocol summary

Study aim
Evaluation of Effectiveness of Oral and Vaginal Misoprostol Administration for Cervical Ripening in Women Before Operative Hysteroscopy
Design
Clinical trial with control group, with parallel groups, double blind, randomized, phase 3 on 126 patients. Block method was used for randomization
Settings and conduct
A randomized double blind clinical trial study was performed in Golestan province, Gorgan, Sayad Shirazi Hospital
Participants/Inclusion and exclusion criteria
Inclusion criteria : Based on the indications for hysteroscopy Exclusion criteria : Contraindications to anti-prostaglandin drugs (asthma, or glaucoma) Women who are contraindicated in hysteroscopy (pregnancy, inflammatory bowel diseas
Intervention groups
Group A, misoprostol 400 microgram tablets vaginally (2 pieces 200 micrograms) and B6 tablets orally (2 pieces), for group B, B6 tablets vaginally (2 pieces) and misoprostol 400 mg tablets orally (2 pieces 200 micrograms))
Main outcome variables
Cervical Ripening in Women Before Operative Hysteroscopy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220102053602N1**
Registration date: **2022-03-16, 1400/12/25**
Registration timing: **prospective**
Last update: **2022-03-16, 1400/12/25**
Update count: **0**
Registration date
2022-03-16, 1400/12/25

Registrant information
Name
Atefeh Mehralitabar
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-04, 1401/01/15
Expected recruitment end date
2022-09-21, 1401/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Effectiveness of Oral and Vaginal Misoprostol Administration for Cervical Ripening in Women Before Operative Hysteroscopy: A Double-Blind Randomized Placebo Controlled Clinical Trial

Public title
Evaluation of Effectiveness of Oral and Vaginal

Misoprostol Administration for Cervical Ripening in Women Before Operative Hysteroscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Based on the indications for hysteroscopy

Exclusion criteria:

Contraindications for anti-prostaglandin drugs (asthma, or glaucoma) Women who are contraindicated for hysteroscopy (pregnancy, inflammatory bowel disease, malignancy)

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

To perform randomization in the samples, we use the block method with six blocks. From the following blocks, we first select one at random and divide the samples into 3 groups according to the order. (A for the vaginal group and B for the oral group and C for the placebo group) C C B B A A 1 A C C B B A 2 A A C C B B 3 B A A C C B 4 B B A A C C 5 C A A B B C 6

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients and physicians evaluating the interventions designed in the study or the consequences after the procedure (gynecology assistant and gynecological laparoscopic surgery fellowship) will not be aware of the group in which the patient is being examined. All interventions in all three groups will be designed similarly and the process will be the same on all samples in all groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, Gorgan,Shastkola road, Philosophical Higher Education Complex

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-10-03, 1400/07/11

Ethics committee reference number

IR.GOUMS.REC.1400.253

Health conditions studied

1

Description of health condition studied

Cervical Ripening

ICD-10 code

N93.9

ICD-10 code description

Abnormal uterine and vaginal bleeding, unspecified

Primary outcomes

1

Description

Cervical Ripening

Timepoint

12 Hours

Method of measurement

Hegar dilator

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Misoprostol 400 micrograms tablets vaginally (2 pieces 200 micrograms, Samisaz pharmaceutical company, Iran) and B6 tablets orally (2 pieces, Aminpharma company, Iran)

Category

Treatment - Drugs

2

Description

Intervention group: B6 tablets vaginally (2 pieces) and misoprostol 400 mg tablets orally (2 pieces of 200 micrograms)

Category

Treatment - Drugs

3

Description
Control group: B6 tablets orally and B6 tablets vaginally (two each)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sayyad Shirazi Hospital
Full name of responsible person
Dr. Mahbobeh Azadehrah
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Philosophical Higher Education Complex, Shast Kola Road, Gorgan
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Sponsors / Funding sources

1

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Gorgan University of Medical Sciences
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info@goums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Atefeh Mehralitabar Firoozjah
Position
Resident
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Gynecology and Obstetrics
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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
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
Only part of the data, such as information about the main outcome or the like, can be shared.
When the data will become available and for how long
Start of access period 6 months after printing results
To whom data/document is available
It will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Use of data to complete the research process on the effects of oral and vaginal misoprostol on cervical preparation in hysteroscopic women
From where data/document is obtainable
Contact the author of the article responsible for the research project data.
What processes are involved for a request to access data/document
Contact the author of the article responsible for the research project data.Specify the type of results requested.
Comments