Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of vaginal hyoscine butyl bromide and vaginal misoprostol on cervical ripening before hysteroscopy

Protocol summary

Study aim
Determination and comparison of the effect of vaginal hyoscine butyl bromide with vaginal misoprostol on cervical ripening before hysteroscopy

Design
A randomized, controlled, double-blind, placebo-controlled clinical trial

Settings and conduct
Patients in Imam Ali Hospital in Zahedan will be randomly divided into two groups. Eligible patients will be randomly divided into two groups after explaining the aims and conditions of the study and obtaining informed consent. A, B will be coded, and the patient and the patient's clinical caregiver (patient physician) will not be informed of the patient allocation to the study groups. So the study will be double-blind. The plan is to carry out the general anesthesia with a mask. Anesthetic drugs are provided under the anesthesia service. After general anesthesia with the mask, the patient is placed in a speculum lithotomy position. If the cervical opening is open the bogey number 5 will be rejected and will be affected and if the open is not opened, other bogeys will be used as needed.

Participants/Inclusion and exclusion criteria
All women candidates for hysteroscopy aged 18-65 years are not allergic to prostaglandins and hyoscine. They have no history of taking antihypertensive drugs, cardiovascular disease, asthma, glaucoma and will excluded if they do not consent to continue the treatment process.

Intervention groups
The first group receiving hyoscine butyl bromide: This drug will be given vaginally at a dose of 20 mg (2 tablets 10 mg) 4 hours before surgery. Group II Misoprostol recipients: this drug will be given vaginally at a dose of 200 µg 4 hours before surgery.

Main outcome variables
Frequency of Dilator Hagar passage number 5; Duration of surgery in two groups; Severity of pain before and after half an hour in both groups; Side effects; Cervical rippening readiness before hysteroscopy in both groups.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190929044920N1**
Registration date: **2019-12-07, 1398/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-07, 1398/09/16**
Update count: **0**

Registration date
2019-12-07, 1398/09/16

Registrant information

Name
Mahboubeh Borna

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 54 3329 5570

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dr.bornamah@zaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-23, 1398/08/01

Expected recruitment end date
2020-06-21, 1399/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of vaginal hyoscine butyl bromide and vaginal misoprostol on cervical ripening before hysteroscopy

Public title
The effect of vaginal hyoscine butyl bromide on cervical ripening before hysteroscopy

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Women candidates for hysteroscopy Age between 18-65 years

Exclusion criteria:
Dissatisfaction with continuing treatment process Sensitivity to the drugs used Asthma Glaucoma cardiovascular disease Taking antihypertensive drugs Sensitivity to prostaglandins

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly blocked with 4 person blocks

Blinding (investigator's opinion)
Double blinded

Blinding description
Medicines will be coded A, B, and the patient and the clinical caregiver (patient physician) will not be informed of the patient's assignment to the study groups. So the study will be double-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Ali Ebn Abitaleb Hospital, Persian Gulf Expressway

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2019-07-28, 1398/05/06

Ethics committee reference number
IR.ZAUMS.REC.1398.235

Health conditions studied

1

Description of health condition studied
Uterine polyp

ICD-10 code
N84.0

ICD-10 code description
Polyp of corpus uteri

2

Description of health condition studied
endometrial hyperplasia

ICD-10 code
N85.0

ICD-10 code description
Endometrial hyperplasia

3

Description of health condition studied
Submucousal fibroid

ICD-10 code
D25.0

ICD-10 code description
Submucous leiomyoma of uterus

4

Description of health condition studied
Abnormal uterine bleeding

ICD-10 code
N93.9

ICD-10 code description
Abnormal uterine and vaginal bleeding, unspecified

5

Description of health condition studied
Noninflammatory disorder of uterus, unspecified

ICD-10 code
N85.9

ICD-10 code description
Noninflammatory disorder of uterus, unspecified

6

Description of health condition studied
Patients who are candidates for hysteroscopy
ICD-10 code
N71.9
ICD-10 code description
Inflammatory disease of uterus, unspecified

Primary outcomes

1

Description
Frequency of Dilator Hagar Crossings No. 5
Timepoint
After complete anesthesia
Method of measurement
Hagar Number Five Crossing

2

Description
Duration of operation time
Timepoint
Duration of operation
Method of measurement
Stopwatch

3

Description
Side effects
Timepoint
From medication to discharge
Method of measurement
Complete patient examination

4

Description
Severity of pain
Timepoint
During surgery and half an hour after surgery
Method of measurement
The visual acuity scale (VAS) zero to ten

5

Description
Cervical dilatation rate
Timepoint
Check in operation
Method of measurement
Based on measurements by Hegar and hysteroscopes

Secondary outcomes

1

Description
Duration of operation time
Timepoint
Duration of operation
Method of measurement
Stopwatch

2

Description
Side effects
Timepoint
From medication to discharge
Method of measurement
Complete patient examination

3

Description
Severity of pain
Timepoint
During surgery and half an hour after surgery
Method of measurement
The visual acuity scale (VAS) zero to ten

4

Description
Cervical dilatation rate
Timepoint
Check in operation
Method of measurement
Based on measurements by Hegar and hysteroscopes

Intervention groups

1

Description
Hyosine Butyl Bromide Recipient: This drug will be given vaginally at a dose of 20 mg (2 tablets 10 mg) 4 hours before surgery.
Category
Diagnosis

2

Description
Misoprostol recipient: This drug will be given vaginally at a dose of 200 µg 4 hours before surgery.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ibn Abi Taleb Hospital
Full name of responsible person
Mahbubeh Borna
Street address
Persian Gulf Highway, Salamat Blvd., Ali Ibn Abi Taleb Hospital

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Noor Mohammad Bakhshani
Street address
Deputy of Research and Technology, Student Scientific Research Center, University of Medical Sciences campus, Dr. Hesabi Square, Zahedan
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Email
Msrc@zamus.ac.ir
Web page address
http://msrc.zaums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Mahboubeh Borna
Position
Assistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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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)

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

Not applicable

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