

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 be 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 ripening 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)

##### Phone

+98 54 3329 5570

##### Email address

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

Submucosal 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

**City**  
Zahedan  
**Province**  
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**Postal code**  
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**Phone**  
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dr.mahbobehbrn@gmail.com

## 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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Sistan-va-Balouchestan  
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+98 54 3329 5796  
**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  
**Street address**  
Ali Ibn Abi Talib Hospital, Slamat Blvd., Persian Gulf  
Highway  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**  
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**Position**  
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**Latest degree**  
Medical doctor  
**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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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