

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparing injectable Hyoscine and vaginal misoprostol in cervical ripening before hysteroscopy

Protocol summary

Study aim

A comparative study of the use of hyoscine and misoprostol in reducing complications caused by hysteroscopy

Design

This study is a phase III randomized control trial on 120 participants with two arms including misoprostol and hyoscine group. It is double blind. Randomization is based on Excel program. Demographic data of patients is recorded. hyoscine group get 20 milligrams of intramuscular ampule and the misoprostol group receive 200 microgram tablets vaginally.

Settings and conduct

The study is performed in Mahdie hospital, infertility ward. Cervical preparation is done 4 hours before the procedure and surgeon is not informed about each group, data is asked from the surgeon and analyzed.

Participants/Inclusion and exclusion criteria

All women candidate for hysteroscopy in Mahdie hospital between 1397-1399 entered the trial after filling the informed consent. Exclusion criteria : allergy to prostaglandins and hyoscine previous cervicitis cervical surgery or trauma

Intervention groups

No control group is identified in this study. Misoprostol group received 200 micrograms tablets vaginally 3 hours before hysteroscopy. Hyoscine group received an intramuscular ampule 2 hours before the procedure. Patient and surgeon are not aware of the drug.

Main outcome variables

post-op pain score; misoprostol or hyoscine side effects; uterine perforation; cervical lacerations;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140224016705N13**

Registration date: **2022-11-05, 1401/08/14**

Registration timing: **retrospective**

Last update: **2022-11-05, 1401/08/14**

Update count: **0**

Registration date

2022-11-05, 1401/08/14

Registrant information

Name

zahra heidar

Name of organization / entity

sbmu

Country

Iran (Islamic Republic of)

Phone

+98 21 4461 2416

Email address

dr_zheidar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing injectable Hyoscine and vaginal misoprostol in cervical ripening before hysteroscopy

Public title

Hyoscine before hysteroscopy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All people who underwent hysteroscopy in Mahdieh Hospital

Exclusion criteria:

People who are allergic to prostaglandins or hyoscine. People with a history of cervical injury or surgery. People with active cervical infection. Glaucoma History of cardiovascular disease and tachycardia People have recently been treated with estrogen. pregnancy

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual simple randomization using rand function of Excel software Every patient who is admitted to the hospital and placed in the hysteroscopy operation list is randomly assigned to one of the two groups of hyoscine or misoprostol using Excel software. Every day two to three people visit the hospital and they are allocated to the hyoscine or misoprostol category using randomization software

Blinding (investigator's opinion)

Double blinded

Blinding description

double blind study the treatment or intervention is unknown to (a) the research participant, (b) the individual(s) who administer the treatment or intervention. A placebo intramuscular ampoule is also prescribed for the patients, and in the misoprostol group, a vaginal pill is inserted during the examination.

Placebo

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

Koodakiar street, Shahid beheshti medical university

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-08-27, 1398/06/05

Ethics committee reference number

IR.SBMU.MSP.REC.1398.527

Health conditions studied

1

Description of health condition studied

cervical stenosis,

ICD-10 code

N88.2

ICD-10 code description

Stricture and stenosis of cervix uteri

2

Description of health condition studied

Endometrial polyp

ICD-10 code

N84.0

ICD-10 code description

Polyp of corpus uteri

Primary outcomes

1

Description

cervical lacerations rate

Timepoint

during hysteroscopy

Method of measurement

presence of lacerations or canals

2

Description

Entrance of hysteroscope into cervix

Timepoint

Start of hysteroscopy

Method of measurement

Likert scale

3

Description

Uterine perforations

Timepoint

During surgery

Method of measurement

Based on serum deficit or surgeon experience

4

Description

Post-op pain/ use of analgesics

Timepoint

for 24 hours after procedure

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

drug side effects

Timepoint

12 hours after drug administration

Method of measurement

based on patient vital signs and general conditions

Intervention groups

1

Description

Intervention group: Misoprostol. The people of this group are prescribed 200 microgram of misoprostol single dose in the form of vaginal tablets on the morning of the surgery during the examination. cytotec misoprostol is prescribed in Mahdiah hospital.

Category

Prevention

2

Description

Intervention group: Hyoscine. These people are given a 20 mg ampoule of hyoscine purchased from Alborz daru company in the morning which is administered intramuscularly.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdie hospital

Full name of responsible person

Zahra heidar

Street address

Shoush square, shishegarkhane street

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1185817311

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mahdiyeh_hospital@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

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

Dr. Zahra Heidar

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information about patient data that is included in the analysis and data about the main outcome can be shared.

When the data will become available and for how long

6 months after publication

To whom data/document is available

All academic and industrial researchers can access data.

Under which criteria data/document could be used

metanalysis could be done on our data.

From where data/document is obtainable

Applicants must send an e-mail in English stating the reason for using the data and the type of analysis. The email will be answered within 10 working days and the information file will be made available to them.

What processes are involved for a request to access data/document

An email will be sent in English stating the reason for using the data and the type of analysis and will be answered within 10 working days.

Comments