

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative effect of nitroglycerin and misoprostol on cervical ripening before hysteroscopy

Protocol summary

Study aim

Determination of the comparative effect of nitroglycerin and mesoprostol in cervical preparation before hysteroscopy

Design

Two parallel group randomised Trial with doubleblinded outcome assesment

Settings and conduct

Questionar rasool akram hospital/ For the first intervention group (42 patients) pearl nitroglycerin 0.4 mg in the recovery room from half to one hour before surgery to a maximum of 3 pearls every 5 minutes with the permission of an anesthesiologist will be implanted vaginally in the posterior cervix fornix For the second intervention group (42 patients), a vaginal misoprostol 200 microgram tablet is inserted in the posterior fornix 4 to 6 hours before surgery and the rate of cervical ripening is checked with bouji and probable sideeffects are recorded

Participants/Inclusion and exclusion criteria

The informed consent of the patient, women of hysteroscopy, lack of nitroglycerin sensitivity, lack of cardiovascular diseases, unstable state of patient/Exclusion criteria:Patients with systolic blood pressure less than 100 mm Hg, intravascular volume reduction, heart disease, severe bleeding, multiparous (Gravid ≥ 2 NVD), inability to use nitroglycerin based on the anesthesiologist's sensitivity to any preservative, history of cerebral hemorrhage, anemia, glaucoma, hyperthyroidism, heart problems

Intervention groups

Two types of intervention are considered The first intervention group (42 patients) Pearl nitroglycerin 0.4 mg in the recovery room one to half hour before the operation up to a maximum of 3 pearls every 5 minutes with the permission of the anesthesiologist will be implanted vaginally in the posterior cervical fornix and For the second intervention group (42 patients), a misoprostol 200 microgram tablet is inserted in the

posterior fornix 6hour before Operation

Main outcome variables

Measurment of dilation before hysteroscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220203053929N1**

Registration date: **2022-04-20, 1401/01/31**

Registration timing: **prospective**

Last update: **2022-04-20, 1401/01/31**

Update count: **0**

Registration date

2022-04-20, 1401/01/31

Registrant information

Name

Melika Ansarin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4465 7764

Email address

melika.ansarin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative effect of nitroglycerin and misoprostol on cervical ripening before hysteroscopy

Public title
Comparative effect of nitroglycerin and misoprostol on cervical ripening before hysteroscopy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
: Conscious patient satisfaction, hysteroscopic women, lack of nitroglycerin sensitivity, without cardiovascular disease lack of existence of severe bleeding, as well as unstable status
Exclusion criteria:
Systolic blood pressure less than 100 mm Hg, intravascular volume reduction, valvular heart disease, severe bleeding, multiparous (NVD 2 ≥ Gravid,) impossibility of using nitroglycerin based on anesthesiologist's sensitivity to any food preservative) Use of hypertension or cardiac drugs for cerebral hemorrhage, anemia, glaucoma, hyperthyroidism, heart problems, heart failure, liver and kidney disease, hypotension and dissatisfaction with continuing the company

Age
From **20 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**
More than 1 sample in each individual
Number of samples in each individual: **42**
Recipient of Misoprostol and Nitroglycerin Recipient Group

Randomization (investigator's opinion)
Randomized

Randomization description
randomization/In this study, with a sample size of 84 individuals, 42 balls for the misoprostol intervention group and 42 balls for the nitroglycerin group were placed in a lottery container and then the balls were randomly removed from the container without replacement and the sequence created was recorded.

Blinding (investigator's opinion)
Double blinded

Blinding description
Outcome assessors and data analysts will not have information on how to assign groups to patients in groups A and B. We divide the outcome assessor and the patient data analyzer into A and. B know and do not

know the nature of groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Science
Street address
No344, block7, 2nd phase, Ekbatan town
City
Tehran
Province
Tehran
Postal code
1396813733
Approval date
2022-03-26, 1401/01/06
Ethics committee reference number
1401.26

Health conditions studied

1

Description of health condition studied
Cervical ripening before hysteroscopy

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Cervical ripening, bleeding measurment, gravidity, parity, abortion number andside Effects like vomiting, hypotension, dizziness, stomach pain, diarehea, fever

Timepoint
Before hysteroscopy and after using Medicine land Side Effects after using

Method of measurement
Cervical dilation with measured dilator, bleeding Mount :pad percentage, pain score, weight :kg, gravidity :pregnancy count/parity:living birth delivery, sideeffect like diarehea, flushinv, hypotension, dizziness, headache, fever, nausea and vomiting

Secondary outcomes

1

Description

Pain score and Mount of bleeding and dilation after hysteroscopy

Timepoint

Before hysteroscopy and after medications

Method of measurement

Pad percentage, pain score, measurment of dilation with measured dilator bouji

Intervention groups

1

Description

Intervention group: nitroglycerin is used in post fornix vaginal for cervical ripening in nuli Gravid women who are candidate for hysteroscopy. In this double-blind clinical trial on 84 women in the age range of 20 to 60 years who were randomly divided into two groups of 42 people in 6-block blocks. Two types of intervention are considered. The first intervention group (42 patients) Pearl nitroglycerin 0.4 mg in the recovery room one to half an hour before the operation up to a maximum of 3 pearls every 5 minutes with the permission of the anesthesiologist will be implanted vaginally in the posterior cervical fornix and For the second intervention group (42 patients), a misoprostol 200 microgram tablet is inserted in the posterior fornix 4 to 6 hours before surgery and the rate of cervical ipening is evaluated with calibrated dilators in both groups. The amount of bleeding and pain before surgery in two Groups are compared

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool akram hospital

Full name of responsible person

Shahla mirgaloo bayat

Street address

No344, entrance 3, block7, phase2, Ekbatan town

City

Tehran

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Postal code

1396813733

Phone

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Email

Melika.ansarin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Research and technology deputy

Street address

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Shahla mirgaloo bayat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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City

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shahla mirgaloo bayat

Position

Associate Processor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Assistant Processor

Latest degree

Specialist

Other areas of specialty/work

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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

Comparative effect of nitroglycerin and mesoprostol in cervical ripening

When the data will become available and for how long

8months

To whom data/document is available

Cosultant Processors

Under which criteria data/document could be used

Cervical ripening before hysteroscopy /based on relative information in proposal can be conducted

From where data/document is obtainable

Melika.ansarin@gmail.com

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

The implementation process of the project in Rasool Akram Hospital is eight months and after that it will be published as an article

Comments