Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative effect of sublingual Nitroglycerin and sublingual Misoprostol on Cervical ripening before Hysteroscopy

Protocol summary

Study aim
Comparison of sublingual nitroglycerin and misoprostol on cervical ripening before hysteroscopy.

Design
This is a double-blind randomized clinical trial, in which 84 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
This study will be conducted at Hazrat Rasool Akram Hospital, where patients will provide written consent by signing and dating the consent form. The degree of cervical preparation will be measured using a graduated dilator in two groups of patients who will receive either nitroglycerin or misoprostol. The study will be double-blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18-50 years (reproductive age), history of at least one Normal Vaginal Delivery, and being a candidate for hysteroscopy. Exclusion criteria: history of drug allergy and cardiovascular diseases.

Intervention groups
Intervention group 1: 42 patients under general anesthesia receive nitroglycerin (Zahrawi Company, Iran) at a dosage of 0.4 mg sublingually 30 minutes before the operation. Intervention group 2: 42 patients receive misoprostol tablets (manufactured by Zahrawi Pharmaceutical Company) at a dosage of 200 micrograms sublingually 6 hours before surgery.

Main outcome variables
Cervical dilatation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191123045476N4**
Registration date: **2023-09-01, 1402/06/10**
Registration timing: **registered_while_recruiting**
Last update: **2023-09-01, 1402/06/10**
Update count: **0**

Registration date
2023-09-01, 1402/06/10

Registrant information

Name
Samaneh Rokhgireh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-20, 1402/03/30

Expected recruitment end date
2024-01-20, 1402/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative effect of sublingual Nitroglycerin and sublingual Misoprostol on Cervical ripening before Hysteroscopy

Public title
Investigating nitroglycerin and misoprostol on cervical ripening

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age between 18-50 years (reproductive age) history of at least one Normal Vaginal Delivery being a candidate for hysteroscopy
Exclusion criteria:
history of drug allergy cardiovascular diseases

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the main researcher and the data analyst will be blinded to the assignment of the study groups; The patients are given a special code and the analyst does not know which group A and B are, and the main researcher is not involved in the selection of patients and does not know which group the patient who is undergoing surgery belongs to.

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 Sciences

Street address
Iran University of medical sciences, Hammat highway, Tehran

City
Tehran

Province
Tehran

Postal code
1445613131

Approval date
2023-05-28, 1402/03/07

Ethics committee reference number
IR.IUMS.REC.1402.180

Health conditions studied

1

Description of health condition studied
Hysteroscopy candidate patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cervical dilatation

Timepoint
Immediately after taking the drug during surgery

Method of measurement
In the operating room, the opening of the cervix is measured in millimeters using sized dilators.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: 42 patients under general anesthesia receive sublingual nitroglycerin (Zahrawi Company, Iran) at a dosage of 0.4 mg 30 minutes before the operation.

Category
Treatment - Drugs

2

Description
Intervention group 2: 42 patients receive misoprostol tablets (manufactured by Zahrawi Pharmaceutical Company) at a dosage of 200 micrograms sublingually 6 hours before surgery.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool Akram Hospital

Full name of responsible person
Samaneh Rokhgireh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Samaneh Rokhgireh

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
No - There is not 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
After the article is published, confidential information such as patient and hospital details will be removed and other information will be provided to the researchers.
When the data will become available and for how long
After publishing the article
To whom data/document is available
Medical specialists
Under which criteria data/document could be used
Medical professionals can access the data for research purposes.
From where data/document is obtainable
Refer to the email of the responsible author.
What processes are involved for a request to access data/document
Official and academic email to the responsible author
Comments