# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Jun 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)

**Phone**
+98 21 6650 9283

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rokhgireh.s@iums.ac.ir

**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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**Full name of responsible person**
Reza Falak

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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 scientific inquiries

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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**