# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

# Randomized double blind placebo-controlled clinical trail comparison vaginal with sublingual misoprostol in preoperative ripening of the cervix before operative -diagnostic hystroscopy in premenopausal women in mirzakuchak-khan hospital at 2010-2011

## Protocol summary

**Summary**

This is a randomized double blind placebo-controlled clinical trial study designed to evaluate the efficacy of 400 micg of misoprostol prescript sublingual, in comparison with vaginal prescription, on cervical ripening before curative or diagnostic hysteroscopy. 100 patients were randomly assigned to the following treatment regimen . The vaginal group received 400 micg of misoprostol (placed into the posterior vaginal fornix) and at the same time received one tablet of vitamin B6 as placebo. The sublingual group received 400 micg of misoprostol sublingually and at the same time received one tablet of vitamin B6 as placebo. Duration of cervical dilatation time in with 9 hegar could be inserted and the complications of hysteroscopy (cervical tearing, creation of a false track, uterine perforation and bleeding) were interpreted as the outcome. The inclusion criteria: woman who gave consent for operative-diagnostic hysteroscopy, and were of reproductive age(i.e; were premenopausal) and not pregnant at the time of presentation. The exclusion criteria: contraindication to PGs(history of severe asthma, glaucoma, preexisting cardiac disease, hypertension, or renal failure), significant uterovaginal prolapsed precluding the administration of vaginal tablets, or history of cervical surgery or cervical incompetency, women who had sub mucosal fibroma larger than 2 cm (because of partial dilatation of cervix).

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201012272576N3**
Registration date: **2011-04-06, 1390/01/17**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

**Registration date**

2011-04-06, 1390/01/17

**Registrant information**

**Name**
Fatemeh Davari Tanha
**Name of organization / entity**
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research., Tehran university of medical scienes

**Expected recruitment start date**

2010-05-22, 1389/03/01

**Expected recruitment end date**

2011-05-22, 1390/03/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Randomized double blind placebo-controlled clinical trail comparison vaginal with sublingual misoprostol in preoperative ripening of the cervix before operative - diagnostic hystroscopy in premenopausal women in

mirzakuchak-khan hospital at 2010-2011

**Public title**
Randomized double blind placebo-controlled clinical trial comparison vaginal with sublingual misoprostol in preoperative ripening of the cervix before operative - diagnostic hysteroscopy in premenopausal women in Mirzakuchak-khan hospital at 2010-2011
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
The inclusion criteria: woman who gave consent for operative-diagnostic hysteroscopy; and were of reproductive age (i.e.; were premenopausal) ; and not pregnant at the time of presentation." The exclusion criteria: contraindication to PGs (history of severe asthma; glaucoma; preexisting cardiac disease; hypertension, or renal failure); significant uterovaginal prolapsed precluding the administration of vaginal tablets; or history of cervical surgery or cervical incompetency; women who had sub mucosal fibroma larger than 2cm (because of partial dilatation of cervix).
**Age**
From **14 years** old to **50 years** old
**Gender**
Female

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **100**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Tehran University of Medical Sciences
**Street address**
Keshavarz Blvd, Ghods Ave, Tehran University of Medical Sciences
**City**
Tehran
**Postal code**
Iran
**Approval date**
2010-06-20, 1389/03/30
**Ethics committee reference number**
9724

## Health conditions studied

**1**

**Description of health condition studied**
Hysteroscopy
**ICD-10 code**
N88.9
**ICD-10 code description**
Non inflammatory disorder of cervix uteri, unspecified

## Primary outcomes

**1**

**Description**
Duration of cervical dilatation time in with 9 hegar could be inserted after prescription of sublingual or vaginal misoprostol
**Timepoint**
6houres after prescription of sublingual or vaginal misoprostol
**Method of measurement**
The largest hegar that could be passed without resistance was starting time of dilatation

## Secondary outcomes

**1**

**Description**
complications of hysteroscopy
**Timepoint**
6hours after misoprostol prescription
**Method of measurement**
clinical

## Intervention groups

**1**

**Description**
100 patients were randomly assigned to the following treatment regiment . The vaginal group recieved 400micg of misoprostol one time six hours before hysteroscopy (placed into the posterior vaginal fornix) and at the same time recieved one tablet of vit B6 sublingualy as placebo. .
**Category**
Treatment - Drugs

**2**

**Description**
The sublingual group received 400micg of misoprstol

sublingually one time six hours before hysteroscopy and at the same time received one tablet of vitB6 as placebo

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Mirza Kochak Khan Hospital, Tehran, Iran

**Full name of responsible person**

Fateme Davari Tanha

**Street address**

Mirza kochakkhan Hospital, Ostad nejatolahi Avenue, Tehran, Iran

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research., Tehran university of medical science

**Full name of responsible person**

Miss Rahmani

**Street address**

Vice chancellor for research, Tehran University of Medical Science, Ghods Avenue, Keshavarz Blvd, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research., Tehran university of medical science

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tehran University ofMedical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Other areas of specialty/work**

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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)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*