

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study on compare of sublingual, rectal and vaginal misoprostol for cervical priming 12 hours before hysteroscopy

Protocol summary

Summary

Randlist software used to divide patients into 6 groups randomly. 100 mcg sublingual misoprostol in group one, 100 mcg rectal misoprostol in second group and 100 mcg vaginal misoprostol in third group were taken. 200 mcg sublingual misoprostol in fourth group, 200 mcg rectal misoprostol in fifth group and 200 mcg vaginal misoprostol in sixth group were taken. 12 hours before hysteroscopy be placed in posterior vaginal fornix. Cervix dilation start in Lithotomy position of 4 hegar dilator before hysteroscopy until first resistance. Dilator number recorded in first resistance and duration between first resistance to hegar 9 dilation recorded. Then hysteroscopy was done and start and end time recorded. Hysteroscopy done with hystroscope with 7mm pod or resectoscope with 9mm external pod. Factors are examined include degree of cervical dilatation before hysteroscopy, dilatation to 9 Hegar length and duration of hysteroscopy, uterine and cervical complications (like bleeding, uterine rupture, cervical laceration and false).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105296626N1**
Registration date: **2011-07-26, 1390/05/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-26, 1390/05/04

Registrant information

Name

Seddighe Abdollahi fard

Name of organization / entity

Tabriz university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 41 1330 4250

Email address

dr-abdollahi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Science

Expected recruitment start date

2011-04-07, 1390/01/18

Expected recruitment end date

2011-09-06, 1390/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on compare of sublingual, rectal and vaginal misoprostol for cervical priming 12 hours before hysteroscopy

Public title

Study on compare of sublingual, rectal and vaginal misoprostol for cervical priming 12 hours before hysteroscopy

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: All the patients who need diagnostic hysteroscopy and surgery such as: irregular uteral bleeding; inter uteral lesions in hysterossalpangography or sonography. Exclusion criteria: pregnancy; urinary tract infection; history of previous cervix surgery; cervix failure; patient dissatisfaction and prohibition

prostaglandin intake

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Science

Street address
Azadi ave, Golgasht ave, Tabriz University of Medical Science

City
Tabriz

Postal code

Approval date
2011-04-06, 1390/01/17

Ethics committee reference number
5/4/321

Health conditions studied

1

Description of health condition studied
Patients who are candidates for hysteroscopy

ICD-10 code
N85.9

ICD-10 code description
Noninflammatory disorder of uterus, unspecified

2

Description of health condition studied
Patients who are candidates for hysteroscopy

ICD-10 code
N71.9

ICD-10 code description
Inflammatory disease of uterus, unspecified

Primary outcomes

1

Description
Cervix dilation for hysteroscopy

Timepoint
During hysteroscopy

Method of measurement
Hegar

Secondary outcomes

1

Description
Reduce hysteroscopy's complications

Timepoint
After hysteroscopy

Method of measurement
By examination

2

Description
Reduce pain during hysteroscopy

Timepoint
During hysteroscopy

Method of measurement
Ask from patient

Intervention groups

1

Description
100 mcg sublingual misoprostol 12 hours before hysteroscopy,

Category
Diagnosis

2

Description
200 mcg sublingual misoprostol 12 hour before hysteroscopy

Category
Diagnosis

3

Description
100 mcg rectal misoprostol 12 hour before hysteroscopy

Category
Diagnosis

4

Description

200 mcg rectal misoprostol 12 hour before hysteroscopy
Category
Diagnosis

5

Description
100 mcg vaginal misoprostol 12 hour before hysteroscopy
Category
Diagnosis

6

Description
200 mcg vaginal misoprostol 12 hour before hysteroscopy
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
AL-Zahra hospital
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of medical science
Full name of responsible person
Vise chancellor research of tabriz university of medical science
Street address
azadi ave, golgasht ave, tabriz university of medical science
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz university of medical science, AL-zahra hospital
Full name of responsible person
Seddighe Abdollahi
Position
Associate Professor
Other areas of specialty/work
Street address
South artesh ave, Bagh shomal crossroad, Al_zahra hospital
City
Tabriz
Postal code
Phone
+98 41 1553 9161
Fax
Email
dr-abdollahi@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Full name of responsible person
Paria Sedaghi
Position
Other areas of specialty/work
Street address
City
Tabriz
Postal code
Phone
Fax
Email
paria_sedaghi@yahoo.com
Web page address

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