Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8831 3955

Email address

fdavaritanha@sina.tums.ac.ir

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

Fateme Davari Tanha

Position

Assistant professor

Other areas of specialty/work

Street address

Mirza Kuchak Khan Hospital, Ostad Nejatolahi Ave, Tehran, Iran

City

Tehran

Postal code

15978

Phone

+98 21 8889 7761

Fax

Email

fatedavari@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fateme Davari Tanha

Position

Assistant professor

Other areas of specialty/work

Street address

Mirza Kuchak Khan Hospital, Ostad Nejatolahi Ave, Tehran, Iran

City

Tehran

Postal code

15978

Phone

+98 912 193 1231

Fax

Email

fatedavari@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of medical science

Full name of responsible person

Fateme Davari tanha

Position

Assistant professor

Other areas of specialty/work

Street address

Mirza Kuchak Khan Hospital, Ostad Nejatolahi Ave, Tehran, Iran

City

Tehran

Postal code

15978

Phone

+98 219121931231

Fax

Email

fatedavari@yahoo.come

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