

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effect of vaginal Misoprostol and vaginal Isoniazid for cervical ripening prior to hysteroscopy procedures in postmenopausal and premenopausal women: Randomized Clinical Trial

Protocol summary

Summary

The aim of this clinical trial study is to compare the efficacy of vaginal misoprostol and isoniazid for cervical ripening prior to hysteroscopy surgery. Inclusion criteria: postmenopausal women and premenopausal women who have no history of vaginal delivery, not pregnant at the time of examination, no contraindication for receiving prostaglandin, no severe vaginal prolapse, no previous surgery on cervix or cervical incompetence. Exclusion criteria: history of vaginal delivery, pregnancy, severe vaginal prolapse, previous surgery on cervix, history of cervical insufficiency, simultaneous laparoscopy and cervical myoma. After confirming the inclusion criteria and obtaining the written informed consent, they randomly assigned to one of two groups, either receiving 400 micrograms of misoprostol vaginally or 3 tablets of 300 mg isoniazid 10-12 hours before operation. The way of randomization into two groups, randomly using Excel software for it. Also to blinding of patients and researchers, used of hide the sealed envelopes. The primary outcomes of the study is interring the hysteroscopy without cervical dilation, and secondary outcomes are number and percentage of patients requiring cervical dilatation, maximum Hagar size interring without force and the side effects. Eventually these outcomes compare in two groups. The sample size in each group is 50 people.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112821506N4**
Registration date: **2016-05-17, 1395/02/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-17, 1395/02/28

Registrant information

Name

Ladan Haghighi

Name of organization / entity

Iran Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 64345

Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Science

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vaginal Misoprostol and vaginal Isoniazid for cervical ripening prior to hysteroscopy procedures in postmenopausal and premenopausal women: Randomized Clinical Trial

Public title

Comparison the effect of vaginal Misoprostol and vaginal

Isoniazid for cervical ripening prior to hysteroscopy procedures

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: postmenopausal women and premenopausal women who have no history of vaginal delivery, not pregnant at the time of examination, no contraindication for receiving prostaglandin, no severe vaginal prolapse, no previous surgery on cervix or cervical incompetence. Exclusion criteria: history of vaginal delivery, pregnancy, severe vaginal prolapse, previous surgery on cervix, history of cervical insufficiency, simultaneous laparoscopy and cervical myoma.

Age

From **15 years** old to **55 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

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 Science

Street address

Iran, Tehran, Hemat Highway, Milad Tower

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.IUMS.REC.1394 .26541

Health conditions studied

1

Description of health condition studied

Abnormal uterine and vaginal bleeding, unspecified

ICD-10 code

N93.9

ICD-10 code description

Abnormal uterine and vaginal bleeding, unspecified

Primary outcomes

1

Description

Hysteroscopy entrance without cervical dilatation

Timepoint

During surgery

Method of measurement

Hagar size

Secondary outcomes

1

Description

The number and percent of patients needs for cervical dilatation

Timepoint

During surgery

Method of measurement

Counting

2

Description

Maximum Hagar size interring without forces

Timepoint

During surgery

Method of measurement

Hagar

Intervention groups

1

Description

Intervention group: 12-10 hours prior to surgery, the use of vaginal misoprostol much as 400 micrograms

Category

Diagnosis

2

Description

Control group: 12-10 hours before the operation, taking 3 tablets of 300 mg isoniazid vaginal

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-e-Akram hospital

Full name of responsible person

Dr. Ladan Haghighi

Street address

Niayesh Av, Sattar khan st, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali Javad Musavi

Street address

Vice chancellor for research, Iran University of
Medical Sciences

City

Tehran

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

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

Iran University of Medical Science

Full name of responsible person

Ladan Haghighi

Position

Professor of Obstetrics and Gynecology

Other areas of specialty/work

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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