Effect of vaginal misoprostol on cervical priming for diagnostic dilatation and curettage

Protocol summary

Summary
The purpose of the present study is to evaluate the effect of vaginal misoprostol on priming the cervix before dilatation in patients who are candidate for this procedure. Methods: A randomized clinical trial was performed on 60 women who were candidate for dilation and curetage. In 30 patients (case group), 200 micro gram misoprostol (one tablet) was administered in posterior fornix of vagina 4 hours before operation, whereas in other 30 patients (control group), placebo was used. Then the two groups were compared according to their need to Hegar dilator thinner than number 5 for dilatation of cervix and the duration of dilatation and curettage.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201110084868N3
Registration date: 2011-12-20, 1390/09/29
Registration timing: registered while recruiting

Recruitment status
Recruitment complete
Funding source
vice-chancellor for research, Qazvin university of medical sciences and health services

Expected recruitment start date
2010-09-23, 1389/07/01
Expected recruitment end date
2020-01-21, 1398/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of vaginal misoprostol on cervical priming for diagnostic dilatation and curettage

Public title
use of vaginal misoprostol for cervical ripening

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: patients with abnormal uterine bleeding who are candidate for dilation and curetage exclusion criteria: systemic diseases; cervical and vaginal infections; history of allergy to prostaglandins; severe anemia or coagulopathy; anticoagulant therapy; history of cervical surgery; pregnancy; lactation; menopause; suspicious endocervical or exocervical erosions;

Age
From 27 years old to 50 years old

Gender
Female

Phase
2
Groups that have been masked

No information

Sample size

Target sample size: 60

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
Qazvin, university of medical sciences and health services

Street address
Qazvin

City
Qazvin

Postal code
Approval date
2010-09-22, 1389/06/31

Ethics committee reference number
28/20/4418

Health conditions studied

1

Description of health condition studied
Diseases of the genitourinary system

ICD-10 code
N92

ICD-10 code description
Excessive, frequent and irregular menstruation

Primary outcomes

1

Description
dilation of cervix as much as hegar dilator numbr five

Timepoint
four hour after using drug

Method of measurement
passage of hegar dilator numbr five

Secondary outcomes

1

Description
Decrease in operation time

Timepoint
During operation

Method of measurement
Measurement with chronometer

Intervention groups

1

Description
Intervention: 30 patients misoprostol one tablet (200 micro gr) was inserted in the vagina 4 hours before surgery for one time.

Category
Treatment - Other

2

Description
Control: In 30 patients one placebo tablet was inserted in vagina 4 hours before surgery for one time.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kosar Hospital

Full name of responsible person
Dr Khadijeh Elmizadeh

Street address
, Taleghni street, Kosar Hospital, Qazvin City

City
Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
vice- chancellor for research, Qazvin univercity of medical sciences and health services

Full name of responsible person
Dr Saeed Asefzadeh

Street address
Shahid Bahonar Blv, Qazvin City

City
Qazvin

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, Qazvin university of medical sciences and health services

**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**
empty

**Type of organization providing the funding**
empty

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**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**
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**Full name of responsible person**
Dr Khadijeh Elmizadeh

**Position**
Obstetrician and Gynecologist

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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