Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jan 2021

Effect of vaginal misoprostol on cervical priming ic 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 curettage. 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

Last update:
Update count: 0
Registration date
2011-12-20, 1390/09/29

Registrant information
Name
Khadijeh Elmizadeh
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Qazvin University of Medical Sciences
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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 ic 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 curettage 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

Double blinded

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 streeet, 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

Person responsible for general inquiries

Contact
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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