Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of sublingual misoprostol on intraoperative blood loss prior to abdominal hysterectomy.

Protocol summary

Summary

This is a Single-blind randomized controlled clinical trial will be done in Imam Reza hospital in Kermanshah Iran. Inclusion criteria: all women undergoing abdominal hysterectomy for benign gynecologic disease and Exclusion criteria include patients who have contraindications to misoprostol, including mitral stenosis, heart disease, glaucoma, sickle cell anemia, severe hypertension, diastolic blood pressure above 100 mm / hg, severe asthma, or known hypersensitivity to prostaglandins, known endometriosis patients with a history of pelvic or active disease, diabetes, obesity (BMI> 30), a history of previous myomectomy and previous use of GnRH agonists before surgery, patients with invasive cancer endometrial, cervical and ovarian tumors. It is estimated sample size of 60 patients in the study group (1) 2 tablets of 200 mcg misoprostol an hour before practice and in the control group (placebo) pill vitamin B6 two an hour before the operation placed under the tongue. The primary outcome measure of intra operative blood lost include blood collection obtained by bottles suction and the weight difference between wet and dry gauze. Length of surgery from incision to skin closure, Hb level before and 24 hour after surgery, need to transfusion, length of hospital stay and fever ask secondary outcome measure will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610224025N8**
Registration date: **2016-11-22, 1395/09/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-11-22, 1395/09/02

Registrant information

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Anisodowleh Nankali
Name of organization / entity
Kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sublingual misoprostol on intraoperative blood loss prior to abdominal hysterectomy.

Public title

sublingual misoprostol on intraoperative blood loss prior to abdominal hysterectomy.

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: all women undergoing abdominal hysterectomy for benign gynecologic disease and

Exclusion criteria include patients who have contraindications to misoprostol, including mitral stenosis, heart disease, glaucoma, sickle cell anemia, severe hypertension, diastolic blood pressure above 100 mm /Hg, severe asthma, or known hypersensitivity to prostaglandins, known endometriosis patients with a history of pelvic or active disease, diabetes, obesity (BMI> 30), a history of previous myomectomy and previous use of GnRH agonists before surgery, patients with invasive cancer endometrial, cervical and ovarian tumors.

Age
No age limit
Gender
Female

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kermanshah University of Medical Sciences
Street address
Kermanshah -Sorkhe Lyzheh-medical School
City
Kermanshah
Postal code
6714869914
Approval date
2015-10-20, 1394/07/28
Ethics committee reference number
kums.rec.1394.133

Health conditions studied

1

Description of health condition studied
Hysterectomy
ICD-10 code
XIV Diseas
ICD-10 code description
N99-N99 Other disorders of the genitourinary system

Primary outcomes

1

Description
blood loss
Timepoint
intra operative
Method of measurement
Total blood volume in the suction bottle + weight difference between dry and wet gauze

Secondary outcomes

1

Description
Postoperative hemoglobin
Timepoint
24 hours after surgery
Method of measurement
blood test

2

Description
Degree of fever after surgery
Timepoint
24 hours after surgery
Method of measurement
Thermometer

3

Description
Length of stay in hospital
Timepoint
From admission to exit
Method of measurement
day

4

Description
The need for blood transfusions
Timepoint
Intraoperative and postoperative
Method of measurement
On hemoglobin level and Severity of bleeding

Intervention groups

1

Description
Population study Will be divided into two groups. study group(Group 1) and control group (Group 2).In study

group 2 pills equal to 400 mcg misoprostol and in control Group 2 pills vitamin B6 will be placed under the tongue one hour before the surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza teaching hospital

Full name of responsible person

Dr. Tayebe Noori

Street address

Kermanshah, Sorkhalyzhe, Imam Reza teaching hospital

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research Kermanshah University of Medical Sciences

Full name of responsible person

Dr . Behrooz Hamzeh

Street address

Kermanshah, shahid Beheshti Blvd., Building No. 2,Vice Chancellor for Research and Technology

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice President of Research Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Tayebe Noori

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Kermanshah University of Medical Sciences Sorkhe Lyzheh- Imam Reza teaching hospital-Office of Women's Education

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Person responsible for scientific inquiries

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Dr Anisodowleh Nankali

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Associate Professor Kermanshah University of Medical Sciences,

Other areas of specialty/work

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Kermanshah University of Medical Sciences

Full name of responsible person

Tayebe Noori

Position

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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