Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of a Single Preoperative Dose of Sublingual Misoprostol on Intraoperative Blood Loss During Total Abdominal Hysterectomy

Protocol summary

Study aim
Determining the effect of a single preoperative dose of sublingual Misoprostol on intraoperative blood loss during total abdominal hysterectomy.

Design
Randomized clinical trial, with control group, two arm parallel group, double blind, 3th phase.

Settings and conduct
The study population include women who were nominated for abdominal hysterectomy due to benign gynecologic diseases in the Rasool Akram and Firoozgar Hospitals in Tehran. In this double-blind randomized clinical trial, surgeons and patients are blinded about the administered tablets (misoprostol or vitamin B6).

Participants/Inclusion and exclusion criteria
Inclusion criteria:nominated patient for abdominal hysterectomy due to benign gynecologic disease
Exclusion criteria:contraindication for misoprostol and malignant disease

Intervention groups
In the intervention group, 1 tablets of misoprostol 200 µg and in the control group (placebo) 1 tablets of vitamin B6 40 mg are administered sublingually one hour before surgery.

Main outcome variables
The amount of bleeding during surgery; post-operation hemoglobin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180821040844N1**
Registration date: **2018-12-06, 1397/09/15**
Registration timing: **retrospective**

Last update: **2018-12-06, 1397/09/15**
Update count: **0**

Registration date
2018-12-06, 1397/09/15

Registrant information

Name
Vahideh Astaraei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-10-23, 1396/08/01

Expected recruitment end date
2018-04-21, 1397/02/01

Actual recruitment start date
2017-11-22, 1396/09/01

Actual recruitment end date
2018-05-05, 1397/02/15

Trial completion date
2018-05-05, 1397/02/15

Scientific title
Effect of a Single Preoperative Dose of Sublingual Misoprostol on Intraoperative Blood Loss During Total Abdominal Hysterectomy

Public title
Effect of a Single Preoperative Dose of Sublingual Misoprostol on Intraoperative Blood Loss During Total Abdominal Hysterectomy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patient who were Nominated for Abdominal Hysterectomy due to Benign Gynecologic Disease
Exclusion criteria:
Misoprostol Contraindication Malignant Gynecologic Disease

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **132**
Actual sample size reached: **132**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are assigned to intervention and control groups, using random sequences generated by SPSS software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Surgeons and patients will be blind about the administered tablets (misoprostol or vitamin B6).

Placebo
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
Hemmat Highway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶-۱۴۵۳۵

Approval date
2018-04-07, 1397/01/18

Ethics committee reference number
IR.IUMS.FMD.REC1396.9311290001

Health conditions studied

1

Description of health condition studied
Bleeding during hysterectomy

ICD-10 code
N99

ICD-10 code description
Intraoperative and postprocedural complications and disorders of genitourinary system, not elsewhere classified

Primary outcomes

1

Description
The amount of bleeding during surgery.

Timepoint
during surgery (from incision until suturing) and immediately after surgery.

Method of measurement
Sum of the measuring the suctioned blood with the absorbed blood in sterile gauzes (assessing the weight difference between bloody gauzes and dry ones)

Secondary outcomes

1

Description
Post-operation hemoglobin

Timepoint
24 hours after surgery

Method of measurement
Blood sample (g/dl)

Intervention groups

1

Description
Intervention group: one tablets of misoprostol (200 µg) were administered sublingually one hour before surgery.

Category
Prevention

2

Description
Control group: One tablets of vitamin B6 (40 mg) were administered sublingually one hour before surgery.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool Akram and Firoozgar Hospitals of Tehran
Full name of responsible person
Vahideh Astaraei
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Rasool Akram and Firoozgar Hospitals,Maziar Mansuri Ave., Satar Khan Ave.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
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Dr Morteza Naserbakht
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research@iums.ac.ir
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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
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Vahideh Astaraei
Position
Resident
Latest degree
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Gynecology and Obstetrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable