

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3879 5777

Email address

vahideh.astaraei@yahoo.com

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

۱۴۹۹۶-۱۴۵۳۵

Approval date

2018-04-07, 1397/01/18

Ethics committee reference number

IR.IJMS.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

Street address

Rasool Akram and Firoozgar Hospitals, Maziar Mansuri Ave., Satar Khan Ave.,

City

Tehran

Province

Tehran

Postal code

98888678881

Phone

+98 21 8364 3512

Fax**Email**

Vahideh.astaraei@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr Morteza Naserbakht

Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

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

Full name of responsible person

Vahideh Astaraei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Vali-e-asr square, Karim Khan Zand street, Beh Afarin street

City

Tehran

Province

Tehran

Postal code

1593747811

Phone

+98 21 8214 1201

Email

vahideh.astaraei@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Vahideh Astaraei

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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