

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison between use sublingual misoprostol and blood loss during myomectomy

Protocol summary

Summary

The purpose of this study is comparing between use sublingual misoprostol and blood loss during myomectomy. inclusion criteria: Over 18 years old; anemia due to AUB; uterine myoma under 8cm in sonography; were enrolled and exclusion criteria: known bleeding disease; active asthma; high diastolic blood pressure; recent NSAIDS use; known hepatic disease; severe anemia; allergy and recent received packed cell. This study is a double blind randomized clinical trial and all patients with uterine myoma in Gynecologic clinic of Rasool Akram Hospital from AUG 2013 to OCT 2014 were included. Sample size was 64 and participants were randomized into two intervention and control groups. In intervention group, patients received 200 micrograms sub lingual misoprostol 1 hour before surgery. Control group received placebo. We used basic hemoglobin and check hemoglobin after 6, 24, 48 after surgery for assessing reduction of bleeding during surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071414621N1**

Registration date: **2014-07-20, 1393/04/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-20, 1393/04/29

Registrant information

Name

Mansureh Vahdat

Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Deputy of Research-Iran University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between use sublingual misoprostol and blood loss during myomectomy

Public title

Comparison between use sublingual misoprostol and blood loss during myomectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Over 18 years old; anemia due to Abnormal uterine bleeding; uterine myoma under 8cm in sonography. Exclusion criteria: known bleeding disease; active asthma; high diastolic blood pressure; recent NSAIDS use; known hepatic disease; severe anemia; allergy and recent received packed cell .

Age

From **18 years** old to **60 years** old

Gender

Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

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

Iran University of Medical Sciences

Street address

Tehran-Hemmat highway-Central bilding of Iran
University of Medical Sciences - Deputy of Research

City

Tehran

Postal code

Iran

Approval date

2014-07-14, 1393/04/23

Ethics committee reference number

93/105/1889 د

Health conditions studied

1

Description of health condition studied

Uterine myoma

ICD-10 code

N85.8

ICD-10 code description

Other specified noninflammatory disorders of uterus

Primary outcomes

1

Description

Bleeding

Timepoint

Preparation,6 & 24& 48 hours after surgery

Method of measurement

Check of hemoglobin(CBC)

Secondary outcomes

empty

Intervention groups

1

Description

In treatment group 200 micrograms sub lingual
misoprostol 1 hour before surgery

Category

Treatment - Drugs

2

Description

In control group placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Obstetrics and Gynecologic Department of Rasool
akram Hospital

Full name of responsible person

Dr Sara Asadollah

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research- Iran University of Medical
Sciences

Full name of responsible person

Deputy of Research-Iran University of Medical
Sciences-Dr Mosavi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research- Iran 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***City**

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Gynecologic Department**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*