Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of outcomes and complications of vaginal misoprostol Preoperative administration of oxytousin infusion during surgery to reduce bleeding during abdominal myomectomy

Protocol summary

Summary

The aim of the study was to reduce bleeding during myomectomy via laparotomy in patients with uterine myoma is due to include women with uterine myoma laparotomy candidates and Interested to participate in the study and no Allergies for misoprostol or oxytocin and No consumption hormonal therapy Before surgery, no active liver or heart or renal or Pulmonary disorders or hypertention and Coagulopathy. 105 female candidates for abdominal myomectomy referred to Zahra Hospital Medical Center are selected . infusion oxytocin 30 unit into 1000 ml normal saline speed of 120 ml/hour before starting anesthesia to Removing the compelete uterine from pelvic (35 patients) and misoprostol single dose of 400 mcg vaginally one hour before surgery during the operation the size of the oxytocin group received normal saline, recommends that (35 cases) treated by routine non adminestration drug before and during surgery during the same volume of saline recommends that oxytocin group (35 cases) on bleeding during myomectomy patients will be compared . For each of the study groups during the monitoring routine hemodynamic variables , primary outcome of reducing bleeding as bleeding (the blood in suction and blood is absorbed in sponges to long Gas 50 cc and gas 5 ml) It is estimated and Subsequent outcome hemoglobin before and after the surgery and the need for blood transfusion and durtion of hospitalization and durtion of surgery as measured by the three groups will be compared .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050210901N6**

Registration date: **2014-05-09, 1393/02/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-09, 1393/02/19

Registrant information

Name

Parvin Mostafa Gharebaghi

Name of organization / entity

Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

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Recruitment status

Recruitment complete

Funding source

Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2013-11-29, 1392/09/08

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcomes and complications of vaginal

misoprostol Preoperative administration of oxytousin infusion during surgery to reduce bleeding during abdominal myomectomy

Public title
The effect of misoprostol on myomectomy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: the desire to participate in the study Exclusion Criteria: allergy to misoprostol or oxytocin; hormone therapy before surgery or gonadotropin releasing drugs such as oral contraceptive pills; active liver disorders - kidney disease - heart - lung ; candidates hysteroscopic myomectomy; hypertension ;coagulopathy
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **105**
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
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences
Street address
Army Street, Baghshomal Circle,Alzahra Hospital
City
tabriz
Postal code
Approval date
2014-03-15, 1392/12/24
Ethics committee reference number
5/4/11808

Health conditions studied

1

Description of health condition studied
Uterine myoma
ICD-10 code
D25.9
ICD-10 code description
Leiomyoma of uterus, unspecified

Primary outcomes

1

Description
Bleeding
Timepoint
Day intervention
Method of measurement
The blood volume (amount of suction blood and blood absorbed in sponges to longGas 50cc and gas 5cc)

Secondary outcomes

1

Description
Duration of hospital stay
Timepoint
Since the intervention to patient discharge from the hospital
Method of measurement
documentation in the file

2

Description
Duration of surgery
Timepoint
Begin operation until the completion of surgery
Method of measurement
documentation in the file

3

Description
hemoglubin 6 hours after Surgery
Timepoint
6 hours after intervention
Method of measurement
Testing the file

4

Description
hemoglubin 24 hour after surgery
Timepoint
24 hours after intervention
Method of measurement
Testing the file

5

Description

blood transfusion

Timepoint

Since the intervention to patient discharge from the hospital

Method of measurement

documentation in the file

Intervention groups

1

Description

infusion oxytocin 30 unit into 1000 ml normal saline speed of 120 ml/hour before starting anesthesia to Removing the compelete uterine from pelvic

Category

Prevention

2

Description

A single dose of 400 mcg of misoprostol vaginally one hour before surgery

Category

Prevention

3

Description

non adminestration drug before and during surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahra hospital

Full name of responsible person

sakineh alizadeh

Street address

Army Street, Baghshomal Circle,Alzahra Hospital

City

tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Female Reproductive Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Ms. Oshaghi

Street address

Al Zahra Hospital - Women's Reproductive Research Center, Tabriz University of Medical Sciences

City

tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Female Reproductive Research Center, Tabriz 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

Resident Obstetric

Full name of responsible person

Sakineh Alizadeh doctor

Position

Tabriz University of Medical Sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Doctor Parvin Mostafaa Gharabaghi

Position

Oncology fellowship of women

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Sakineh Alizadeh

Position
Resident Obstetric

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