Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative of Effects of Sublingual Misoprostol and Infusion Oxytocin in Reduction of Bleeding at Cesarean

Protocol summary

Summary

This study aimed to compare the effect of 200 micrograms sublingual misoprostol , 400 micrograms sublingual misoprostol and 20 IU Oxytocin in reduction of bleeding during cesarean section. One hundred eighty candidate for Cesarean section with Incision in Lower Segment of uterus, in Imam Reza Hospital during 2011-2012 were included in this randomized, prospective, double-blind and placebo-controlled study. Patients were divided into three equal groups randomly. Group I received 200 micrograms sublingual misoprostol plus 200 micrograms sublingual placebo , Group II received 400 micrograms sublingual misoprostol ,Group III received 400 micrograms placebo sublingually and infusion of 20 IU oxytocin in 1 mL normal saline (300 mL/h), just after fetal expulsion. the calculated blood loss was based on gathered blood in suction dish and the number of bloody gases. this calculation was performed by an educated but unaware nurse.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109104025N4**
Registration date: **2011-12-12, 1390/09/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-12-12, 1390/09/21

Registrant information

Name

Anisodowleh Nankali

Name of organization / entity

Kermanshah University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Kermanshah University of Medical Sciences.

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative of Effects of Sublingual Misoprostol and Infusion Oxytocin in Reduction of Bleeding at Cesarean

Public title

Comparison of Effects of Sublingual Misoprostol and Infusion Oxytocin in Reduction of Bleeding at Cesarean

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Elective or Emergency Cesarean Deliveries with Incision in Lower Segment of uterus, Gestational Age more than 37 Weeks Exclusion criteria:Anemia;Multiple pregnancy;Polyhydraminus;Prolonged labor;Premature rupture of membrane, History of diabetes mellitus,Hypertension,Cardiovascular disease,coagulopathy disorders, Placenta Previa &

Placenta Abruption, Vaginal Bleeding.

Age
From **15 years** old to **44 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical sciences.

Street address
Building number2,Shahid Beheshti blvd.

City
Kermanshah

Postal code

Approval date
2011-06-14, 1390/03/24

Ethics committee reference number
73521/024/7/پ

Health conditions studied

1

Description of health condition studied
Child birth and priperium

ICD-10 code
O00-O99

ICD-10 code description
O60-O75

Primary outcomes

1

Description
Intraoperative bleeding

Timepoint
At the time of surgery

Method of measurement
Measured with the blood suctioned in cc by the graded container

Secondary outcomes

1

Description
Fever

Timepoint
During 48 hrs after surgery, measured every 3 hours

Method of measurement
Persist fever more than 38 ° c, with thermometer

2

Description
Change in basal pulse rate

Timepoint
Before surgery & intraoperative & 6 hrs after surgery

Method of measurement
Pulse rate in one minute

3

Description
Changing of blood pressure

Timepoint
Before surgery & intraoperative & 6 hrs after surgery

Method of measurement
Measuring with Sphygmomanometer

4

Description
Diarrhea

Timepoint
Before & 6 hrs after surgery

Method of measurement
question about change in frequency of defecation or its consistency (watery stool)

5

Description
Vomiting

Timepoint
Before & 6 hrs after surgery

Method of measurement
Question about forceful expulsion of stomach contents

Intervention groups

1

Description
Intervention group:sublingual misoprostol 200micrograms Control groups:Infusion20 unit oxytocin,misoprostol 400 micrograms
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
obstetrics & gynecology department,Imam Reza Hospital
Full name of responsible person
Soudabeh Eshghiali
Street address
obstetrics & gynecology department,Imam Reza Hospital,Parastar Blvd,Kermanshah University of Medical Sciences
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Imam Reza Hospital,Parastar blvd,Sorkheh lyjeh,Kermanshah University of Medical Sciences (KUMS) , Kermanshah,Iran
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of 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 (KUMS)
Full name of responsible person
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Person responsible for scientific inquiries

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City

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Web page address

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