

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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

Iran (Islamic Republic of)

Phone

+98 83 1427 6310

Email address

anankali@kums.ac.ir

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

Kermanshah

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

Dr.Soudabeh Eshghi ali

Position

Obstetrics & Gynecology resident

Other areas of specialty/work

Street address

obstetrics & gynecology department,Imam Reza
Hospital,Parastar blvd,Sorkheh lyjeh,Kermanshah
University of Medical Sciences (KUMS) ,
Kermanshah,Iran

City

Kermanshah

Postal code

Phone

+98 912 580 8928

Fax

Email

atusaeshghi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences (KUMS)

Full name of responsible person

Anisodowleh Nankali

Position

obstetrics & gynecology assistant professor

Other areas of specialty/work

Street address

obstetrics & gynecology department,Imam Reza
Hospital,Parastar blvd,Sorkheh lyjeh,Kermanshah
University of Medical Sciences (KUMS) ,
Kermanshah,Iran

City

Kermanshah

Postal code

67144-15333

Phone

+98 83 1427 6310

Fax

Email

anankali@kums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Sara Daeeshin

Position

Obstetrics (BCs) Of Maternity Research Center

Other areas of specialty/work**Street address**

obstetrics & gynecology department, Imam Reza
Hospital, Parastar blvd, Sorkheh lyjeh, Kermanshah
university of medical sciences (KUMS) ,
Kermanshah, Iran

City

Kermanshah

Postal code**Phone****Fax****Email****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