Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparison of rectal and sublingual Misoprostol on decreas Post - Partum haemorrhage during cesarean section

Protocol summary

Study aim
Comparison of rectal and subcutaneous administration of misoprostol in bleeding during and after cesarean section

Design
Randomized clinical trial on two intervention groups of rectal misoprostol and sublingual misoprostol

Settings and conduct
This randomized double-blind clinical trial study will be performed on 80 pregnant women who referred to Shahid Sadoughi Hospital in Yazd for elective cesarean section. Mothers will be randomly divided into two groups. Immediately after the birth of the infant, 20 units of oxytocin will be infused in 500 ml ringer serum in both groups. In the first group 400 µg rectal misoprostol will be administered after spinal anesthesia and in the second group 400 µg sublingual misoprostol.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Pregnant women (gestational age 37 and older), singleton pregnancy, and those who are candidates ofcesarean section Exclusion criteria:Fetal Distress, Macrosomia, Sensitivity to misoprostol, Previa, and Polyhydramnios

Intervention groups
This study included two intervention groups. The intervention group one consisted of 40 single-term pregnant women (gestational age 37 weeks and older) who were candidates for cesarean section and received rectal misoprostol.The intervention group two consisted of 40 pregnant women with similar conditions and received sublingual misoprostol.Both intervention groups received placebo during the intervention.

Main outcome variables
count of bleeding during and after delivery of cesarean section

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190204042614N1**
Registration date: **2020-03-01, 1398/12/11**
Registration timing: **retrospective**

Last update: **2020-03-01, 1398/12/11**
Update count: **0**

Registration date
2020-03-01, 1398/12/11

Registrant information

Name
Nooshin Hatamizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3822 4000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2018-12-31, 1397/10/10

Actual recruitment start date
2018-05-01, 1397/02/11

Actual recruitment end date
2019-01-21, 1397/11/01

Trial completion date
2019-01-21, 1397/11/01

Scientific title
A comparison of rectal and sublingual Misoprostol on decreas Post -Partum haemorrhage during cesarean section

Public title
A comparison of rectal and sublingual Misoprostol on Post -Partum haemorrhage during cesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women who were candidates of Cesarean section
Exclusion criteria:
pregnancy induced hypertension twin pregnancy sensitivity to prostaglandin fetal distress
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
using convenient sampling method, the patients were selected. then, the patients were randomly assigned to two groups of rectal and sublingual using random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
Researcher and student
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences Yazd
Street address
Professor Hesabi Blvd, Shohadaye Gomnam Blvd, Medical Sciences Pardis
City
Yazd
Province
Yazd
Postal code
8915173149
Approval date
2018-03-12, 1396/12/21
Ethics committee reference number
IR.SSU.MEDICINE.REC.1396.271

Health conditions studied

1

Description of health condition studied
bleeding during and after cesarean section
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Hemoglobin before and after surgery
Timepoint
6 hours after surgery
Method of measurement
Cell counter machine

2

Description
Hematocrit before and after surgery
Timepoint
6 hours after surgery
Method of measurement
Cell counter machine

Secondary outcomes

1

Description
Blood pressure
Timepoint
Every 5 minutes during surgery, every 15 minutes in recovery
Method of measurement
Device monitoring

2

Description
Heart beat
Timepoint
Every 5 minutes during surgery, every 15 minutes in recovery
Method of measurement
Device monitoring

Intervention groups

1

Description
Intervention group: Rectal misoprostol is prescribed at a dose of 400 µg after spinal anesthesia. Placebo is also prescribed with rectal misoprostol.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: sublingual misoprostol is prescribed at a dose of 400 µg after spinal anesthesia. Placebo is also prescribed with rectal misoprostol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital in Yazd
Full name of responsible person
Nooshin hatamizadeh
Street address
Shahid Qandi Boulevard, Avicenna Street, Yazd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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medschool@ssu.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Nooshin Hatamizadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

Contact
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Afsar sadat Tabatabaee
Position

Associate Professor

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Specialist

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Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available