Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of prophylactic misoprostol versus tranexamic acid in reduction of postpartum hemorrhage in candidate patients for cesarean in Amir Al-Momenin hospital, Semnan.

Protocol summary

Summary

Objectives: Considering the importance of postpartum hemorrhage and finding a way for lowering the complications of postpartum hemorrhage especially maternal mortality, this study is designed to compare the effect of misoprostol and tranexamic acid in reducing of postpartum hemorrhage. Design: This study is blinded clinical trial and patients after informed consent will enrolled and divide into three groups. Setting and conduct: Two hundred and eighty five patients who fulfill inclusion criteria will enroll in study after informed consent and will be randomly divided into three groups and interventions perform on them. Participants and major inclusion and exclusion criteria: Pregnant women candidates for elective cesarean with gestational age 37 weeks or more, singleton pregnancy with cephalic presentation, will be enrolled. Patients with preeclampsia, multiple pregnancies, premature birth, prolonged rupture of the membranes, abnormal placental-binding, systemic diseases and sensitivity to prostaglandins are excluded. Intervention: Cesarean section will done under spinal anesthesia. Group A will receive 400 micrograms of misoprostol rectal (as 2 tablets of 200 mcg) and group B receive Tranexamic acid, 10mg/kg 30 minutes before operation as intravenous infusion during 20 minutes. Main outcome measures (variables): The main outcome is the amount of blood lost and hemoglobin and hematocrit values.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102511504N6**
Registration date: **2015-12-17, 1394/09/26**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-12-17, 1394/09/26

Registrant information

Name

Sanam Moradan

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Semnan University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of prophylactic misoprostol versus tranexamic acid in reduction of postpartum hemorrhage in candidate patients for cesarean in Amir Al-Momenin hospital, Semnan.

Public title
Effects of Misoprostol versus Tranexamic acid in reduction of postpartum hemorrhage after cesarean
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Candidates for elective cesarean section; gestational age 37 weeks or more; singleton pregnancy with cephalic presentation. Exclusion criteria: Preeclampsia; multiple pregnancies; premature birth; prolonged rupture of the membranes; abnormal placental-binding; systemic diseases; sensitivity to prostaglandins.
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **285**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Commettee of Semnan University of Medical Sicenses
Street address
Basidj Boulevard
City
Semnan
Postal code
3519747167
Approval date
2015-09-23, 1394/07/01
Ethics committee reference number
IR.SEMUMS.REC.1394.75

Health conditions studied

1

Description of health condition studied
Postpartum hemorrhage
ICD-10 code
O72
ICD-10 code description
Postpartum haemorrhage

Primary outcomes

1

Description
Volume of Blood Loss
Timepoint
During surgery
Method of measurement
Measuring of blood lost and counting of blood soaked gauze pieces

Secondary outcomes

1

Description
Hematocrite and Hemoglubin
Timepoint
24 horses after surgery
Method of measurement
Laboratory test

Intervention groups

1

Description
Group A: Cesarean section will do under spinal anesthesia. Patients receive 400 micrograms of misoprostol rectal (as 2 tablets of 200 mcg).
Category
Treatment - Drugs

2

Description
Groupe B: Cesarean section will done under spinal anesthesia. Patients receive Tranexamic acid, 10mg/kg 30 minutes before operation as intravenous infusion during 20 minutes.
Category
Treatment - Drugs

3

Description
Group C: Cesarean section will do under spinal anesthesia. Patients will not receive any treatments except standard and usual therapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al Momenin hospital
Full name of responsible person
Roya Mahdavi Anaraki
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Semnan University of Medical Science
Full name of responsible person
Mohammad Reza Asgari
Street address
Basidj Boulevard
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Semnan
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 Semnan University of Medical Science
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

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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