

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)

Phone

+98 23 1446 0066

Email address

smoradan@sem.ums.ac.ir

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 Committee of Semnan University of Medical Sciences

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 Hemoglobin

Timepoint

24 hours 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

Group 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

Street address

Imam Hussein square

City

Semnan

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

City

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

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Roya Mahdavi Anaraki

Position

Obstetric and Gynecology Resident

Other areas of specialty/work

Street address

Imam Hussein square, Amir Al Momenin Hospital

City

Semnan

Postal code

3519734731

Phone

+98 23 3344 0066

Fax

Email

maryamsina1234@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Science

Full name of responsible person

Dr. Sanam Moradan

Position

Gynecologist/ Associate professor

Other areas of specialty/work

Street address

Amir Al Momenin Hospital, Imam Hussein Square

City

Semnan

Postal code

3519734731

Phone

+98 23 3344 0066

Fax

Email

smoradan@semums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mehrdad Zahmatkesh

Position

Research Expert

Other areas of specialty/work

Street address

Kowsar Hospital, Amin Avenue, Basidj Bulvard

City

Semnan

Postal code

3519899951

Phone

+98 23 3343 7838

Fax

Email

mehrdadzahmatkesh@semums.ac.ir

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