Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison the effect of intravenous Tranexamic Acid and sublingual Misoprostol and Oxytocin to reducing of post- cesarean hemorrhage

Protocol summary

Summary

Comparison the effect of intravenous Tranexamic Acid and sublingual Misoprostol and Oxytocin to reducing of post- cesarean hemorrhage. Design:Randomized double blind clinical trial. Setting and conduct: All subjects will randomly devide in two groups of 75 and therapeutic interventions perform. Inclusion criteria are singleton pregnant women with 37- 40 weeks gestational ages, first gravida and maximum second gravida,previous cesarean section with lower segment incision. Exclusion criteria are preeclampsia, abnormal placenta, previous uterine rupture. Intervention: First group will receive 400 micrograms of sublingual Misoprostol after removing placenta.Second group,will injected 1gr of intravenous Tranexamic Acid into 20 c.c of 5% Dextrosewaters slowly before begining cesarean and both groups will receive 20 Units of Oxytocin after removing placenta immediatly. The volume of bleeding will measured by the bottle of suction set after removing placenta,the weight of cesarean set, consumed gases during the cessrean section. The blood pressure and pulse rate will be measured every 5 minutes during the section and every 30 minutes up to an hour after cesarean. Hemoglobin will be measured at the time of entering the ward and 24 hours after cesarean. One hour after cesarean occurrence of side effects such as fever, nausea, shivering will be evaluated. Patients up to 24 hours after cesarean will be monitored and in the event of sever bleeding an uterotonic drugs will be used. Main outcome measures: Hemoglobin values and volume of bleeding during cesarean section.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201708308611N6**
Registration date: **2017-09-20, 1396/06/29**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-09-20, 1396/06/29

Registrant information

Name
Hamideh Pakniat
Name of organization / entity
Qazvin University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 282242452
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hpakniat@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and technology, Qazvin University of Medical Sciences

Expected recruitment start date

2017-01-30, 1395/11/11

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of intravenous Tranexamic Acid and sublingual Misoprostol and Oxytocin to reducing of post- cesarean hemorrhage

Public title

Comparison the effect of intravenous Tranexamic Acid and sublingual Misoprostol and Oxytocin to reducing of

post- cesarean hemorrhage

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria are singleton pregnant women with 37-40 weeks gestational ages, first gravida and maximum second gravida; previous cesarean section with lower segment incision. Exclusion criteria: preeclampsia; abnormal placenta; previous uterine rupture.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The subjects are candidates for emergency or elective cesarean section, which are easily and randomly entered into the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Bahonar Blvd, Qazvin, Iran

City

Qazvin

Postal code

Approval date

2017-01-29, 1395/11/10

Ethics committee reference number

IR.QUMS.REC.1395.282

Health conditions studied

1

Description of health condition studied

Postpartum haemorrhage

ICD-10 code

O72

ICD-10 code description

Postpartum haemorrhage

Primary outcomes

1

Description

Blood pressure

Timepoint

Every 5 minutes during the section and every 30 minutes up to an hour after cesarean.

Method of measurement

Blood pressure monitor

2

Description

Pluse rate

Timepoint

Every 5 minutes during the section and every 30 minutes up to an hour after cesarean.

Method of measurement

Blood pressure monitor

3

Description

volume od bleeding

Timepoint

After removing placenta

Method of measurement

Through suction, weight of cesarean section's set and consumed gases

Secondary outcomes

1

Description

Nausea

Timepoint

One hour after cesarean section

Method of measurement

Ask the patient

2

Description

Hemoglobin

Timepoint

At the time of entering the patient's in the ward and 24 hours after cesarean section

Method of measurement

Blood sample

3

Description

Fever

Timepoint

One hour after cesarean section

Method of measurement

Thermometer

4

Description

Shivering

Timepoint

One hour after cesarean section

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: first group will receive 400 micrograms of sublingual Misoprostol after removing placenta+ receive 20 Units of Oxytocin after removing placenta immediatly

Category

Treatment - Drugs

2

Description

Intervention group: second group,will injected 1gr of intravenous Tranexamic Acid into 20 c.c of 5% Dextrosewaters slowly before begining cesarean+ receive 20 Units of Oxytocin after removing placenta immediatly.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Azarmidokht Shojaei

Street address

Kowsar Hospital, Taleghani St, Qazvin, Iran

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Full name of responsible person

Dr Amir Peymani

Street address

Bahonar Blvd, Qazvin, Iran

City

Qazvin

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 Qazvin 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

Kowsar Hospital

Full name of responsible person

Azarmidokht Shojaei

Position

Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kowsar Hospital

Full name of responsible person

Dr Hamideh Pakniat

Position

Asistant Professor, Department of Obstetrics and Gynecology

Other areas of specialty/work

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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