Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of prophylactic intravenous tranexamic acid on blood loss after cesarean delivery

Protocol summary

Study aim

The aim of this study was to evaluate the effect of preventive injection of tranexamic acid ampules on blood volume lost after cesarean delivery.

Design

In practice, the volume of blood in the suction (the volume of amniotic fluid from the blood that has accumulated in the suction) and the weight of the gauze and blood-stained tampons will be used to check for postpartum hemorrhage. A perfectly wet 4 x 4 cm gas holds about 10 cc of blood (28). A digital scale (with an error rate of 10 grams) will be used to weigh gases and guns. Postpartum hemorrhage is defined as a person losing 1,000 cc or more of blood after a cesarean section. To collect the blood lost after the cesarean section, immediately after the end of the cesarean section, a disposable plastic cover with a certain weight is spread under the cesarean section woman and she will be weighed 2 hours after the cesarean section.

Settings and conduct

The study population included women eligible for cesarean section in Izadi Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria included age 18-35 years, single pregnancy, cesarean delivery, blood pressure less than 140 over 90, no history of thromboembolism, no uterine myoma, no IUFD fetus, no decolonization and no history or active heart disease , Hepatic and renal. During cesarean section, if placental adhesions such as placenta, increta and percorta are observed, individuals will be excluded.

Intervention groups

The case group received 10 mg / kg tranxamic acid ampoule (made by Kharazmi Company) by slow intravenous injection (1 cc / min) immediately before cesarean section and the control group received intravenous sodium chloride (distilled water) ampoule at the same dose as the intervention group. Will receive.

Main outcome variables

Lost blood volume and hemoglobin and hematocrit levels before and 12-24 hours after delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091010002558N7**
Registration date: **2020-12-08, 1399/09/18**
Registration timing: **retrospective**

Last update: **2020-12-08, 1399/09/18**
Update count: **0**

Registration date

2020-12-08, 1399/09/18

Registrant information

Name
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Name of organization / entity
Qom university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-21, 1395/01/02

Expected recruitment end date

2017-04-03, 1396/01/14

Actual recruitment start date

2016-03-21, 1395/01/02

Actual recruitment end date

2017-04-03, 1396/01/14

Trial completion date

2017-04-03, 1396/01/14

Scientific title

Effect of prophylactic intravenous tranexamic acid on blood loss after cesarean delivery

Public title

Effect of prophylactic intravenous tranexamic acid on blood loss after cesarean delivery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria included age 18-35 years, single pregnancy, cesarean delivery, blood pressure less than 140 over 90, no history of thromboembolism and coagulation disease, no uterine myoma, no IUFD fetus, no decolonization and no history or Active heart, liver and kidney diseases

Exclusion criteria:

During cesarean section, if placental adhesions such as placenta, increta and percorta are observed, individuals will be excluded.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

1

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The research population is randomly divided into two groups of intervention and control. Random assignment of patients to two groups is based on the block method. Block size 4 is considered. So we have six quadruple blocks consisting of AABB, ABAB, BBAA, BABA, ABBA, BAAB. The selection of each block will also be random and will be done using dice. For example, if the number 3 is rolled in a dice, the BBAA block is considered, so the first two patients are assigned to treatment B and the next two patients to treatment A. The dice will be thrown ten times to complete the assignment of patients to treatment groups. Assignment of treatment to groups A and B will also be based on accident (coin toss).

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to hide the medication allocation, two vials of the tranexamic acid and distilled water were placed in similar opaque sequentially numbered sealed packages by an Operator room technician that not involved in sampling and analysis, who maintained the medication administration code. In this way, the data evaluators and participants had no knowledge of the study medication.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

saheli street

City

Qom

Province

Ghoum

Postal code

3715835155

Approval date

2016-02-10, 1394/11/21

Ethics committee reference number

MUQ.REC.1394.154

Health conditions studied

1

Description of health condition studied

postpartum blood loss

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

blood loss after cesarean

Timepoint

The lost blood will be controlled in two times: A: The time of placenta departure until the end of cesarean section B: From the end of cesarean section to 2 hours after delivery.

Method of measurement

In practice, the volume of blood in the suction and the weight of the gases and blood-stained tampons will be used to check for postpartum hemorrhage. A digital scale (with an error rate of 10 grams) will be used to weigh gases and guns. To collect the blood lost after the cesarean section, immediately after the end of the cesarean section, a disposable plastic cover with a certain weight is spread under the cesarean section

woman and she will be weighed 2 hours after the cesarean section.

2

Description
hemoglobin and hematocrit levels
Timepoint
Hemoglobin and hematocrit levels will be monitored before and 12-24 hours after delivery.
Method of measurement
hemoglobin and hematocrit are measured by blood test.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Women in the study group, received one gram intravenous TA, 10 min before skin incision in 200 mL normal saline over 10 min. In this study, TA was supplied in 2 × 500 mg/ mL ampoules obtained from kharazmi Pharmaceutical Company in Iran.
Category
Treatment - Drugs

2

Description
Control group: Women in the control group, received 10mL placebo (distilled water) 10 min before skin incision in 200 mL normal saline over 10 min. The placebo comprised 2×5 ml distilled water ampoules from Shahid Ghazi Pharmaceutical Company in Tabriz - Iran.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Izadi hospital
Full name of responsible person
Esmat Jafarbegloo
Street address
Azar street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Doctor Ehsan sharifi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum University of Medical Sciences
Proportion provided by this source
1
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
Ghoum University of Medical Sciences
Full name of responsible person
Esmat Jafarbegloo
Position
Instructor. faculty member
Latest degree
Master
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All of the above are documented and can be sent via email.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in scientific institutes

Under which criteria data/document could be used

Scientific uses to continue the work process or aggregate data

From where data/document is obtainable

To the researcher email

What processes are involved for a request to access data/document

Refer a reputable scientific institution to the applicant via email

Comments