

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Efficacy and Safety of Prophylactic Use of Tranexamic Acid for Decreasing the Blood Loss in Elective Cesarean Section: A Placebo-Controlled Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of the efficacy and safety of tranexamic acid in decreasing the bleeding in elective cesarean section

Design

A double-blind placebo-controlled randomized clinical trial

Settings and conduct

This study was conducted in a tertiary level teaching hospital. Included women were randomly allocated to 2 groups. In first group patients received 1 gram tranexamic acid intravenously just before skin incision. In control group patients received same volume of 5% dextrose as placebo. The volume of blood loss during and 6 hours after surgery were measured by weighting the drapes and sponges before and after use and adding the volume of blood in suction bottle. Volume of bleeding were compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: singleton pregnancies aged between 37 and 42 weeks of gestation Exclusion criteria: patients with Known allergy to TXA, history of thromboembolic or coagulative disorders, history of renal, cardiac or hepatic impairment, gestational or chronic hypertension/pre-eclampsia, placental disorders, polyhydramnios; patients who had received aspirin 1 week before surgery.

Intervention groups

Receiving 1 gram tranexamic acid as bolus just before skin incision

Main outcome variables

Primary outcome was decreased intra-operative and post-operative blood loss in elective CS. Secondary outcome was occurrence of minor or major adverse reactions of TXA (headaches, fatigue, abdominal pain, nausea, vomiting, diarrhea, seizures, anaphylaxis, visual disturbances, pulmonary embolism, deep vein thrombosis, myocardial infarction, cerebrovascular accidents. adverse neonatal outcome and labor

complications like increased uterine contractions and placental separation were also considered as secondary outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180819040830N2**

Registration date: **2020-04-29, 1399/02/10**

Registration timing: **retrospective**

Last update: **2020-04-29, 1399/02/10**

Update count: **0**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

Zahra Naeiji

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 5506 2628

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-29, 1398/12/10

Expected recruitment end date

2020-03-29, 1399/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and Safety of Prophylactic Use of Tranexamic Acid for Decreasing the Blood Loss in Elective Cesarean Section: A Placebo-Controlled Randomized Clinical Trial

Public title

Tranexamic Acid for Decreasing the Blood Loss

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

singleton pregnant women elective cesarean section
gestational age between 37 and 42 weeks

Exclusion criteria:

patients with Known allergy to TXA history of thromboembolic or coagulation disorders known history of renal, cardiac or hepatic impairment gestational or chronic hypertension/pre-eclampsia placental disorders polyhydramnios patients who had received aspirin 1 week before surgery

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

computer-generated blocks of 4, block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient and gynecologist who performed the cesarean section and research assistant who measured the bleeding volume were blinded to the intervention. research assistant who prepared the drug and placebo for administration were open to the intervention.

Placebo

Used

Assignment

Parallel

Other design features

--

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak,

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2018-11-03, 1397/08/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.662

Health conditions studied**1****Description of health condition studied**

peri-operative hemorrhage

ICD-10 code

O72.1

ICD-10 code description

Other immediate postpartum hemorrhage

Primary outcomes**1****Description**

Intra-operative and post-operative blood loss in elective cesarean section

Timepoint

From skin incision to hours after surgery

Method of measurement

Intra-operative blood loss (from skin incision to skin closure) was measured by gravimetric method. Soaked drapes, mops, sponges, pads, and operation table perineal sheet were weighed with an electronic weighing scale before and after the surgery. The difference between their wet and dry weights was considered as the collected blood. Each mg of measured weight was considered as equivalent to 1 ml of blood. The total amount of blood loss (ml) was determined as the sum of blood absorbed by soaked mops, sponges, pads, drapes and perineal sheet plus blood collected in suction bottle after placental delivery (to exclude the measurement of amniotic fluid). Post-operative blood loss (first 6 hours after skin closure) was measured by weighing and numbering the vaginal pads used by the patient.

Secondary outcomes

1

Description

Occurrence of minor or major adverse reactions of tranexamic acid (headaches, fatigue, abdominal pain, nausea, vomiting, diarrhea, seizures, anaphylaxis, visual disturbances, pulmonary embolism, deep vein thrombosis, myocardial infarction, cerebrovascular accidents). adverse neonatal outcome and labor complications like increased uterine contractions and placental separation were also considered as secondary outcomes.

Timepoint

From drug administration to 6 hours after surgery

Method of measurement

History taking, physical exam, para-clinical assessments as indicated

Intervention groups

1

Description

"Intervention group": received a bolus of 1gm TXA (Tranexip®, Tranexamic acid, 500mg/5ml, for slow IV injection, Caspian Tamin Pharmaceutical Co, Tehran, Iran) if their body weight was <90 kg and 1.5 gram if their body weight was >90 kg diluted in 15 ml of 5% dextrose intravenously.

Category

Treatment - Drugs

2

Description

Control group: Receiving routine and 15 ml Dextrose water 5% IV injection as placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdiye hospital

Full name of responsible person

Zahra Naeiji

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Preventative Gynecology Research Center

Proportion provided by this source

30

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Naeiji

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"There is no further information"

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available