Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 e 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
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Iran (Islamic Republic of)
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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®,Tavexamic 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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Shishegar Khane St., Fadayian Eslam Blv. Shoosh Sq.

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zahranaeiji98@yahoo.com

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