Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation the effect of Tranexamic acid infusion with oxytocin versus oxytocin alone before elective cesarean section in prevention preoperative and post operative hemorrhage in Karaj Kamali Hospital: A randomized clinical trial study

Protocol summary

Study aim

Determining the effect of tranexamic acid injection with oxytocin versus oxytocin alone before elective cesarean section in preventing intraoperative and postoperative hemorrhage

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 per 200 patients. Excel software rand function was used for randomization.

Settings and conduct

This study will be performed on patients who are candidates for elective cesarean section referred to Kamali Hospital in Karaj. By random computer numbers in sealed envelopes the anesthesia technician opens the envelope but the surgeon, patient, and data analyst will not be aware of the classification.

Participants/Inclusion and exclusion criteria

Singleton pregnancy, Age over 18 years, Gestational age over 34 weeks, candidate for elective cesarean section, No anemia, No history of underlying disease, No history of bleeding disorders, No risk factor for post partum hemorrhage, No allergy to Tranexamic acid

Intervention groups

In the intervention group, 20 minutes before the operation and incision of the skin, 1 gram of tranexamic acid diluted in 20 cc of 5% extrusion is injected intravenously. In the control group, placebo is used in 20 cc of 5% dextrose. Both groups after the umbilical cord clamp will receive 30 units of oxytocin in 500 cc of Ringer serum intravenously.

Main outcome variables

Reduce post partum hemorrhage and the need for blood transfusions after cesarean section by preoperative injection of tranexamic acid

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211109053019N1**
Registration date: **2022-11-26, 1401/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-26, 1401/09/05**
Update count: **0**

Registration date

2022-11-26, 1401/09/05

Registrant information

Name
Elham Ghafarinia
Name of organization / entity
Alborz 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

2022-11-22, 1401/09/01

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation the effect of Tranexamic acid infusion with oxytocin versus oxytocin alone before elective cesarean section in prevention preoperative and post operative hemorrhage in Karaj Kamali Hospital: A randomized clinical trial study

Public title
Prophylactic effect of Tranexamic acid in decreasing hemorrhage in elective cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Singleton pregnancy Age over 18 years old Gestational age over 34 weeks Hemoglobin level before operation over 10 mg/dl Platelets over 100000 Be an elective cesarean section candidate

Exclusion criteria:
Emergency cesarean section Age less than 18 years old History of deep vein thrombosis or pulmonary emboli History of arterial thrombosis(pectoralis angina, myocardial infarction or stroke) History of convulsion or epilepsy Any known active cardiovascular or liver or kidney disorder Autoimmune disease Sickle cell disease Severe bleeding disease Placenta previa Placenta accreta spectrum Preeclampsia or eclampsia Gestational hypertension or chronic hypertension Hemolysis or low platelet Intrauterine fetal death Allergy to tranexamic acid Multifetal pregnancy Sever polyhydramnios History of recurrent abortion Uterine fibroma History of rheumatologic disease Varicose veins Pre partum hemorrhage Sever intra abdominal adhesions during surgery Damage to bladder or intestines or other organs during surgery Unsuccessful operative vaginal delivery

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Volunteers participating in the study divided into two groups: intervention and control, using a table of computer random numbers in envelopes in the package.

Blinding (investigator's opinion)
Double blinded

Blinding description
After randomizing people, the envelopes in the package are opened by the anesthesia technician and the anesthesiologist is in the process of assigning the grouping but patient and surgeon and person completing the questionnaire and people who did statistical analysis, They do not know the grouping of patients.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Alborz University of Medical Sciences

Street address
Golshahr street

City
karaj

Province
Alborz

Postal code
3198764653

Approval date
2022-08-13, 1401/05/22

Ethics committee reference number
IR.ABZUMS.REC.1401.146

Health conditions studied

1

Description of health condition studied
Post partum hemorrhage after elective cesarean section

ICD-10 code
O72

ICD-10 code description
Postpartum hemorrhage

Primary outcomes

1

Description
Measurement of hemoglobin after cesarean section

Timepoint
24 hours after surgery

Method of measurement
Using laboratory vein blood samples

Secondary outcomes

1

Description
Post partum hemorrhage
Timepoint
24 hours after delivery
Method of measurement
Comparison of hemoglobin before and after surgery and using the formula to estimate the amount of bleeding

Intervention groups

1

Description
Intervention group: The person 20 minutes before the operation and incision of the skin will receive 1 g of tranexamic acid diluted in 20 cc of 5% dextrose intravenously. Also after the umbilical cord clamp, 30 units of oxytocin in 500 cc of Ringer serum will be received intravenously.
Category
Prevention

2

Description
Control group: The person 20 minutes before the operation and incision of the skin will receive placebo in 20 cc of 5% dextrose intravenously. Also after the umbilical cord clamp, 30 units of oxytocin in 500 cc of Ringer serum will be received intravenously.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali Hospital of Karaj
Full name of responsible person
Elham Ghafarinia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Alborz University of Medical Sciences Research Assistant
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj University of Medical Sciences
Proportion provided by this source
100
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
Karaj University of Medical Sciences
Full name of responsible person
Dr Ramesh Baradaran Bagheri
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data can be shared after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Research centers and faculty members
Under which criteria data/document could be used
According to the request of the researcher and the request of the academic staff
From where data/document is obtainable
Send an email to the responsible scientific person
What processes are involved for a request to access data/document
Documents will be sent to the mentioned people within two months from the time of the request and sending the email
Comments