

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2237 8028

Email address

elham.ghafarinia@gmail.com

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

Street address

Beheshti Ave, Kamali street

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Karaj

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr Hamed Mohammadi

Street address

Faculty of Medicine, Campus of the University of Medical Sciences, Nabovat Square

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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

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr Ramesh Baradaran Bagheri

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Dr Elham Ghafarinia

Position

Specialist assistant in obstetrics and gynecology surgery

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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