Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of oral and intravenous Tranexamic Acid for preventing postpartum hemorrhage after cesarean delivery

Protocol summary

Study aim
Effect of oral and intravenous Tranexamic Acid for preventing postpartum hemorrhage after cesarean delivery

Design
A clinical trial with the control group, randomized, single-center trial, Sample size of 100 people.

Settings and conduct
Amir Al-Momenin Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 40 years; Candidate for a non-emergency cesarean section; A singleton pregnancy with a gestational age between 38 and 39 weeks that has been confirmed by ultrasound. Exclusion Criteria: Preeclampsia, premature birth, prolonged rupture of the water sac, multiple births; Visualization of fetal anomalies by ultrasound; Previous history of systemic diseases.

Intervention groups
Intervention group: In this group, according to the protocol, the infusion of one gram of tranexamic acid (two 500 mg TRANEXIP® ampoules manufactured by Caspian Pharmaceutical Company, Iran) in 200 ml of normal saline serum will be done within 10 minutes before on start the operation. Control group: In this group, according to the protocol, 2 grams of oral tranexamic acid (8 capsules of 250 mg TRANCID® manufactured by Amin Pharmaceutical Company of Iran) will be given to the patient one hour before the operation.

Main outcome variables
Blood pressure; Postpartum bleeding volume.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151228025732N78**
Registration date: **2023-07-06, 1402/04/15**
Registration timing: **prospective**

Last update: **2023-07-06, 1402/04/15**
Update count: **0**

Registration date
2023-07-06, 1402/04/15

Registrant information

Name
Alireza Emadi

Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran

Country
Iran (Islamic Republic of)

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are20935@semums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-11, 1402/04/20

Expected recruitment end date
2025-03-18, 1403/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of oral and intravenous Tranexamic Acid for preventing postpartum hemorrhage after cesarean delivery

Public title

Effect of oral and intravenous Tranexamic Acid for preventing postpartum hemorrhage after cesarean delivery

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 40 years Candidate for non-emergency cesarean section A singleton pregnancy with a gestational age between 38 and 39 weeks that has been confirmed by ultrasound

Exclusion criteria:

Preeclampsia, premature birth, prolonged rupture of the water sac, multiple births Visualization of fetal anomalies by ultrasound Previous history of systemic diseases

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 2). Using Excel software to generate random number tables

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient and the midwife who distributes the drugs among the patients will be unaware of the prescribed drug for each patient

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2023-05-22, 1402/03/01

Ethics committee reference number

IR.SEMUMS.REC.1402.038

Health conditions studied

1

Description of health condition studied

Hemorrhage after cesarean delivery

ICD-10 code

O34.21

ICD-10 code description

Maternal care for scar from previous cesarean delivery

Primary outcomes

1

Description

Blood pressure

Timepoint

Before the start of cesarean section and 2 hours after surgery

Method of measurement

Heart monitor device

2

Description

Postpartum bleeding volume

Timepoint

The difference in the weight of sheets, gauze and long gauze used during surgery and up to 2 hours after surgery

Method of measurement

"Mahek" brand digital scale (made in Iran with an accuracy of 0.1 gr)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, according to the protocol, the infusion of one gram of tranexamic acid (two 500 mg TRANEXIP® ampoules manufactured by Caspian Pharmaceutical Company, Iran) in 200 ml of normal saline serum will be done within 10 minutes before on staret the operation.

Category

Treatment - Drugs

2

Description
Control group: In this group, according to the protocol, 2 grams of oral tranexamic acid (8 capsules of 250 mg TRANCID® manufactured by Amin Pharmaceutical Company of Iran) will be given to the patient one hour before the operation.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir Al-Momenin Hospital

Full name of responsible person
Satinik Darzi

Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

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Phone
+98 23 3345 1336

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Sati.darzi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Fatemeh Ehsani

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Semnan University of Medical Sciences, Basij Blvd, Semnan.

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fatemehehsani59@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Sati Nik Darzi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
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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)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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