Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation Efficacy of Tranexamic acid in decreasing blood loss in cesarean delivery

Protocol summary

Study aim

General Purpose : The effect of tranexamic acid on post-cesarean hemorrhage in Motahhari hospital Specific goals: 1. Determine the effect of TXA on reducing post-cesarean hemorrhage based on age of patients 2. Determine the effect of TXA on decreasing post-cesarean hemorrhage based on BMI in patients 3. Determine the effect of TXA on reducing post-cesarean hemorrhage based on parity in patients

Design

Non-probability sampling will be easy (available). Individuals will be randomly assigned to two groups and blocks A and B will be covered. How to Calculate Sample Size: How to Calculate Sample Size: According to the study by Bhavana G et al. In 2016, taking into account the following values and using the sample size formula, with 20% loss, 100 individuals (50 intervention group and 50 control group) were considered.

Settings and conduct

In the study group, the injection of 1.5 g (15) ccTXA before skin incision for cases weighing more than 90 kg and 1 g=10 cc before skin incision for cases weighing less than 90 kg. The control group will also have the same injection rate as the control group, with the exception of distilled water (1.5 g =15 cc) prior to skin incision for cases weighing more than 90 kg (1 g=10 cc) before Skin incision is used for cases weighing less than 90 kg

Participants/Inclusion and exclusion criteria

Single fetus and Elective Cesarean Section Referred to Motahhari Hospital for Delivery

Intervention groups

participants seprate two group with blind method and one group give tranexamic acid.

Main outcome variables

Blood loss after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140420017365N4**
Registration date: **2020-04-27, 1399/02/08**
Registration timing: **retrospective**

Last update: **2020-04-27, 1399/02/08**
Update count: **0**

Registration date

2020-04-27, 1399/02/08

Registrant information

Name

Fatemeh Bahadori

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 7077

Email address

fbahadory27@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation Efficacy of Tranexamic acid in decreasing blood loss in cesarean delivery

Public title
Evaluation Efficacy of Tranexamic acid in decreasing blood loss

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for Elective Singleton Cesarean section Having adequate prenatal care. Complete the form of informed consent Age range 18-45 years

Exclusion criteria:
Patients do not accept to participate in the study They have anemia and bleeding diseases or serious medical or surgical diseases Sensitivity to Tranexamic acid Fetal macrosomia Thromboembolism Score(V.T.E. scoring)≥3 Placental Abruption , placenta parvia and abnormal placental adherence Uterine myoma more than 5 cm Polyhydramnios Multi-fetus pregnancy Use of Anticoagulant such as enoxaparin or heparin Severe pregnancy complications such as preeclampsia Long-term hospitalization more than 3 days before cesarean section

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization method or block randomization. With 8 blocks of patients

Blinding (investigator's opinion)
Triple blinded

Blinding description
Randomized (by Block Randomization method) with 8 blocks of patients (individuals in one of two tranexamic acid recipient groups) study group (or distilled water group) control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Urgent Street, Resalat Blvd, Urmia , Iran

City
Urmia

Province
West Azarbaijan

Postal code
Postal Code:57147833

Approval date
2019-07-31, 1398/05/09

Ethics committee reference number
IR.UMSU.REC.1398.189

Health conditions studied

1

Description of health condition studied
Blood loss after cesarean

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Blood loss

Timepoint
After cesarean section

Method of measurement
Bleeding volume including suctioned blood volume, weight of all draw sheets changed up to 6 hours after surgery

2

Description
Blood transfusion

Timepoint
Blood transfusions and blood products at admission time

Method of measurement
number of transfused blood products

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Intravenus Injection of tranexamic

acid 1.5or1gram to pateints before the onset of cesarean.it is a fibrinolytic agent that reduce the blood loss in surgery.this ampules are 500 mg and we inject two or tree ampule .this ampoules manufactured by caspian tamin.

Category

Treatment - Drugs

2

Description

Control group: Injection of sterilized water 10 or15 cc according to patients BMI ;below 90kg and above 90 kg ;before cesarean section in control group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital

Full name of responsible person

Fatemeh Bahadori

Street address

Kowsar center, Motahhari Hospital, Kashani St., Urmia

City

Urmia

Province

West Azarbaijan

Postal code

57147

Phone

+98 44 3223 7077

Email

bahadory27@yahoo.com

Web page address

https://motahari.umsu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Phone

+98 44 3223 4897

Email

mohebbi_iraj@yahoo.co.uk

Web page address

https://english.umsu.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Maryam Nikpour

Position

rezident of gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

kashani street/Motahari hospital

City

Urmia

Province

West Azarbaijan

Postal code

04412234125

Phone

0442237077

Fax

+98 44 1223 4125

Email

Maryamnikpour1367@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Maryam Nikpour

Position

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Latest degree

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Other areas of specialty/work

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kashani st.motahari hospital

City
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Province
West Azarbaijan

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04412234125

Phone
0442237077

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Maryamnikpour1367@gmail.com

Person responsible for updating data

Contact

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Oroumia University of Medical Sciences

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Phone
0442237077

Email
Maryamnikpour1367@gmail.com

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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Non-demographic data files, including the main study variables, are published online in Excel format.

When the data will become available and for how long
The data will be published after the publication of the protocol paper and the original paper of the study results by the corresponding researcher.

To whom data/document is available
The data will be available online without any request.

Under which criteria data/document could be used
For analysis and study by other interested researchers

From where data/document is obtainable
The data will be available online

What processes are involved for a request to access data/document
The data will be available online without any request.

Comments