Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evalution of prophylactic effect and complication of Tranexamic Acid on blood loss during and after Elective Caesarean Section

Protocol summary

Study aim
Determination of Tranexamic Acid Effects and Its Complications in Prevention of Gestation During and After Cesarean Section

Design
In this study, the prevalence of patients who were candidates for cesarean section in 2019-2020 was initially readily available or available to eligible individuals up to the time of reaching the sample of 100 people. Then, using randomized block method, two groups And they are divided into the group of tranexamic acid and the control group is given normal saline.

Settings and conduct
In this single-blinded study that is done in Imam Ali Hospital, Zahedan, candidates for cesarean section divide into two groups of case and control by random block method. The case group is treated with Tranexamic Acid and the control group is given normal saline. Hemoglobin and gases used during the surgery measure before and six hours after surgery. Candidates evaluate during admission, during cesarean section and 6 weeks after cesarean section through a complications checklist.

Participants/Inclusion and exclusion criteria
Exclusion Criteria: High Body Index, History of venous thrombosis, Uterian myoma, liver and kidney disease, History of High Birth weight, Placenta Previa, Acreta, Pre Eclampsia, Disseminated Intravascular Coagulation Inclusion Criteria: All women who are candidates for cesarean section.

Intervention groups
Intervention group: In this group, patients who are candidates for cesarean section are given10 mg/kg tranexamic acid before surgery and Drug effects and complications are reviewed 6 weeks later. Control group: In this group, patients who are candidates for cesarean section are given a 10 mg/kg Normal saline before surgery and complications are reviewed 6 weeks later.

Main outcome variables
Hemoglobin measure before and six hours after surgery, Counting the gases used during the surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181021041403N1**
Registration date: **2018-12-29, 1397/10/08**
Registration timing: **prospective**

Last update: **2018-12-29, 1397/10/08**
Update count: **0**

Registration date
2018-12-29, 1397/10/08

Registrant information

Name
Nazanin Shahraki ghadimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3328 8399

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-05, 1397/10/15

Expected recruitment end date
2019-05-22, 1398/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evalution of prophylactic effect and complication of Tranexamic Acid on blood loss during and after Elective Caesarean Section

Public title
Evalution of prophylactic effect and complication of Tranexamic Acid on blood loss during and after Elective Caesarean Section

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
All pregnant women who are candidates for elective cesarean section

Exclusion criteria:
High body mass index History of venous thrombosis Uterine myoma Liver and kidney disease History of high birth weight Plasenta previa,acreta and... Pre eclampsia Disseminated Intravascular Coagulation

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, Block

Blinding (investigator's opinion)
Single blinded

Blinding description
After inclusion, patients were randomized to receive either treatment (tranexamic acid group) or Normal Saline (control group). The randomization sequence was generated by a single blinded selection of women in labor for admission, and randomization was balanced by the researcher.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Bahar Complex, No.18 Pirozi Street, Pirozi Ave, Zibashahr Quarter

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9817919411

Approval date
2018-10-10, 1397/07/18

Ethics committee reference number
IR.ZAUMS.REC.1397.288

Health conditions studied

1

Description of health condition studied
Bleeding during and after delivery of cesarean section

ICD-10 code
O82.0

ICD-10 code description
Delivery by elective caesarean section

Primary outcomes

1

Description
Hb value

Timepoint
Hemoglobin measurement before surgery and six hours after surgery

Method of measurement
laboratory kit

2

Description
Number of used gases

Timepoint
Counting the gases used during the surgery

Method of measurement
Gas count

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, patients who are candidates for cesarean section are given10 mg/kg tranexamic acid before surgery and Drug effects and complications are reviewed 6 weeks later.

Category

Treatment - Drugs

2

Description
Control group: In this group, patients who are candidates for cesarean section are given a 10 mg/kg Normal saline before surgery and complications are reviewed 6 weeks later.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali Hospital
Full name of responsible person
Nazanin SharakiGhadimi
Street address
Khalij Fars.Highway
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https://www.iauzah.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr.Mohammad Moein
Street address
Daneshgah Ave , Islamic Azad university
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Nazanin Shahraki Ghadimi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Web page address

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
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
Undecided - It is not yet known if there will be 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