

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Evaluation 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 given 10 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

n.sh.ghadimi@iauzah.ac.ir

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	Ethics Committee of Zahedan University of Medical Sciences
Scientific title	Street address
Evaluation of prophylactic effect and complication of Tranexamic Acid on blood loss during and after Elective Caesarean Section	Bahar Complex, No.18 Pirozi Street, Pirozi Ave, Zibashahr Quarter
Public title	City
Evaluation of prophylactic effect and complication of Tranexamic Acid on blood loss during and after Elective Caesarean Section	Zahedan
Purpose	Province
Prevention	Sistan-va-Balouchestan
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	9817919411
All pregnant women who are candidates for elective cesarean section	Approval date
Exclusion criteria:	2018-10-10, 1397/07/18
High body mass index History of venous thrombosis Uterine myoma Liver and kidney disease History of high birth weight Placenta previa,acreta and... Pre eclampsia Disseminated Intravascular Coagulation	Ethics committee reference number
Age	IR.ZAUMS.REC.1397.288
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	

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 given 10 mg/kg tranexamic acid before surgery and Drug effects and complications are reviewed 6 weeks later.

Category

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

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Emamali.hos@gmail.com

Web page address

<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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

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Phone

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med@iauzah.ac.ir

Web page address

<https://iauzah.ac.ir>

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

Street address

Bahar Complex, No.18 Pirozi Street, Pirozi Ave,
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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Nazanin Shahraki Ghadimi
Position
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Latest degree
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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
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