Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of tranexamic acid in reducing blood loss and intra and postoperative complications in patients with placenta accrete spectrum

Protocol summary

Study aim
Determining the effectiveness of tranexamic acid in reducing bleeding and complications during and after surgery in patients with placenta accrete spectrum syndrome

Design
Patients are randomly divided into tranexamic acid and placebo groups. Randomization is done using the random block method. Saline or tranexamic acid-containing syringes are prepared by an anesthesiologist who is aware of patient grouping but has no role in intraoperative or postoperative management. Also, participants, caregivers and the person analyzing the results will not know about the grouping of patients.

Settings and conduct
The present study will be performed as a double-blind clinical trial on patients undergoing cesarean section with a diagnosis of placenta accrete spectrum in Imam Khomeini Hospital in Ahvaz in 2020-2021.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years, Diagnosis of placenta accrete syndrome on ultrasound, singleton pregnancy, Cesarean section or hysterectomy, Patient consent to participate in the study; Exclusion criteria: history of cardiovascular diseases, history of the bleeding disorder, liver and kidney disease, known coagulation disorders, anemia preoperatively, thrombocytopenia, history of preeclampsia or eclampsia in the current pregnancy, and contraindication to TXA use

Intervention groups
Intervention group: Patients in this group receive 1 gram of intravenous tranexamine within 10 minutes immediately after birth and umbilical cord ligation. Control group: Patients in this group receive 50 mL of normal saline after umbilical cord ligation

Main outcome variables
Amount of estimated blood loss (EBL) during and after surgery, amount of blood products transfusion, complications during and after delivery and duration of hospitalization

General information

Reason for update
Changing sample size and study outcomes, modifying inclusion and exclusion criteria

Acronym

IRCT registration information
IRCT registration number: **IRCT20201003048909N1**
Registration date: **2020-10-26, 1399/08/05**
Registration timing: **retrospective**

Last update: **2021-07-12, 1400/04/21**
Update count: **1**

Registration date
2020-10-26, 1399/08/05

Registrant information

Name
kobra shojaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3338 9635

Email address
amir_fattah2000@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-01, 1399/07/10

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of tranexamic acid in reducing blood loss and intra and postoperative complications in patients with placenta accrete spectrum

Public title

Efficacy of tranexamic acid in reducing blood loss in patients with placenta accrete spectrum

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Diagnosis of placenta accrete spectrum syndrome on ultrasound Singleton pregnancy Cesarean section or cesarean section hysterectomy Patient consent to participate in the study

Exclusion criteria:

History of cardiovascular diseases including coronary artery disease, myocardial infarction, severe arrhythmias, and congestive heart failure history of the bleeding disorder including antiphospholipid syndrome (APS) liver and kidney disease known coagulation disorders anemia preoperatively (hemoglobin level < 8 mg/dl) history of preeclampsia or eclampsia in the current pregnancy contraindication to TXA use (history of TXA allergy, venous thromboembolism, active thrombolytic diseases, acquired color vision disorders, history of seizure, pre-known hematuria, and renal failure

Age

From **18 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **23**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into Intervention group and control groups. Randomization is done using the random block method. Intervention group: Patients in this group receive 1 gram of intravenous tranexamine within 10 minutes immediately after birth and umbilical cord ligation. Control group: Patients in this group receive 50 mL of normal saline after umbilical cord ligation. Saline or tranexamic acid -containing syringes are prepared by an anesthesiologist who is aware of patient grouping but has no role in intraoperative or postoperative management. Also, participants, caregivers and the person analyzing the results will not know about the grouping of patients. During and after surgery, blood loss is closely monitored and Hb levels are constantly monitored. Blood transfusion if Hb level drops below 8 gm / dl, and advanced transfusion protocol is performed if blood loss exceeds 1000 ml, in which case one FFP unit and one platelet unit with each pRBC transfer unit It will be given. If necessary, this meaning is transferred to the ICU

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study will be performed as a double-blind clinical trial on patients undergoing cesarean section with a diagnosis of placenta accrete spectrum in Imam Khomeini Hospital in Ahvaz in 1399. After obtaining written consent, eligible patients are randomly divided into two groups. Syringes containing TXA or normal saline will prepared by an anesthesiologist who knew the groupings but had no role in intraoperative or postoperative management. Also, participants and caregivers will be blinded to the grouping and interventions

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapoor University of Medical Sciences

Street address

Golestan Ave.

City

Ahwaz

Province

Khouzestan

Postal code

6811111111

Approval date

2020-09-26, 1399/07/05

Ethics committee reference number

IR.AJUMS.REC.1399.485

Health conditions studied

1

Description of health condition studied

Placenta accrete spectrum

ICD-10 code

O43.21

ICD-10 code description

Placenta accreta

Primary outcomes

1

Description
Amount of estimated blood loss (EBL)
Timepoint
Before and after surgery
Method of measurement
CC blood lost

2

Description
complications during and after delivery
Timepoint
Evaluating the patient during and after delivery
Method of measurement
Incidence of complications during and after delivery such as rupture of the bowel, need for hysterectomy, hypogastric ligation, need for laparotomy, and rupture of the bladder

Secondary outcomes

1

Description
need to blood products transfusion
Timepoint
during the surgery and the first 24 h after delivery
Method of measurement
Amount of received PRBCs, amount of received platelets, and amount of received FFP

2

Description
duration of hospitalization
Timepoint
Number of hospitalization days after delivery
Method of measurement
Number of hospitalization days

Intervention groups

1

Description
Intervention group: Patients in this group will receive 1 gram of intravenous tranexamic acid brand TRANEXIP® made by Caspian Tamin Pharmaceutical Company during 10 minutes immediately after the birth of the baby and cord closure.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group receive 50 mL normal saline after birth and umbilical cord closure made by Iranian Pharmaceutical and Injectable Products Company. Syringes containing normal saline or tranexamic acid are prepared by an anesthesiologist who is knowledge of the patients' grouping but will not play a role in the management during or after surgery. Also, participants, carers and the person analyzing the results will not know the grouping of patients. Blood transfusion is performed if hemoglobin levels are reduced to less than 8 gm/dl, and advanced transfusion protocol is performed when blood loss exceeds 1000 ml, in which case a unit of fresh frozen plasma (FFP) and a platelet unit with each unit of packed red blood cells (pRBCs) are transferred. Patients will be transferred to the Intensive Care Unit (ICU) if needed
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahwaz Imam Khomeini Educational and Medical Center
Full name of responsible person
Kobra Shojaei
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Azadegan St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Kobra Shojaei
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact
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Medical Student(Resident)
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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
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
Yes - There is 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
Title and more details about the data/document
All data from this study can be published
When the data will become available and for how long
Start access from the time the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data of the present study can be used in any

situation and anywhere

From where data/document is obtainable

Dr maryam saberi behbahani e mail: amir_fattah2000@yahoo.com cell tel : 00989161911268

What processes are involved for a request to access data/document

Correspond or contact the person in charge of providing the documentation

Comments