Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effectiveness of Tranexamic acid in blood loss during and after cesarean section

Protocol summary

Summary

The present randomized, double blind clinical experiment was carried out in 2013-14 at Shariati Hospital of Bandar Abbas, Iran. Two hundred pregnant women who visited this hospital and volunteered to have a cesarean surgery participated in this research. All women between 20 to 40 years of age who were in their 37th to 40th week of pregnancy and had opted for a cesarean surgery entered the study. The following were excluded: those with an experience of twinning; placenta abnormalities; severe pre-eclampsia; macrosomy; polyhydramnios; previous cesarean or abdominal surgeries; kidney, brain, blood or liver disorders; coagulopathy; anemia; thrombophilia; thromboembolic disorders; allergy to Tranexamic acid. In addition, patients whose BMI was higher than 30 were excluded from the study. At the outset, all patients would get the required and adequate information about this research, and can only enter the study with full consent. On entering the research, patients equally divided into two groups following a blocked randomization. In the intervention group, with the help of an anesthesiologist, 20 minutes before the cesarean surgery 10 milligrams of Tranexamic acid for each kilogram of body mass combined with 200 milliliters of normal saline slowly injected within 5 minutes. Patients in the control group received only 200 milliliters of normal saline within 5 minutes. Neither the patient nor the researcher would be informed of the type of group. After the surgery all patients received 10 units of Tranexamic acid injected along with 500 milliliters of normal saline within 20 minutes. Moreover, all patients also received 30 units of oxytocin within the first 8 hours of the surgery. In the case of atonic uterus, 10 more units of oxytocin infusion added. Weight of blood gases and surgical sheets before and after use recorded. It needs to be reminded that amniotic fluid and the blood emerged due to skin incision and abdominal layers would be gathered in another suction and did not enter our estimations. The amount of the blood lost estimated 2 hours after the delivery (based on the difference of the weight of the tampon used). At the outset of the surgery, a tampon was inserted into the vagina, the difference of its weight before the surgery and 2 hours after the surgery was calculated. Therefore, the amount of bleeding is estimated. Hb was checked 24 hours after the cesarean surgery. In case, the level of hemoglobin is lower than 8, blood transfusion was done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100419396N1**
Registration date: **2015-02-09, 1393/11/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-09, 1393/11/20

Registrant information

Name
Razieh Rrajabzadeh
Name of organization / entity
Hormozgan University of Medical Scienes
Country
Iran (Islamic Republic of)
Phone
+98 76 3333 7104
Email address
barvari@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2013-04-22, 1392/02/02

Expected recruitment end date
2013-06-27, 1392/04/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of Tranexamic acid in blood loss during and after cesarean section

Public title
effectiveness of Tranexamic acid in blood loss during and after cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria
All women between 20 to 40 years of age who were in their 37th to 40th week of pregnancy and had opted for a cesarean surgery entered the study. The following were excluded: those with an experience of twinning; placenta abnormalities; severe pre-eclampsia; macrosomy; polyhydramnios; previous cesarean or abdominal surgeries; kidney, brain, blood or liver disorders, coagulopathy; anemia; thrombophilia; thromboembolic disorders; allergy to Tranexamic acid. In addition, patients whose BMI was higher than 30 were excluded from the study.

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hormozgan University of Medical Sciences

Street address
vice chancellor for research and technology, Shahid Mohamadi Hospital

City
Bandar Abbas

Postal code

Approval date
2013-05-08, 1392/02/18

Ethics committee reference number
90-92/149

Health conditions studied

1

Description of health condition studied
caesarean section

ICD-10 code
82

ICD-10 code description
Single delivery by caesarean section

Primary outcomes

1

Description
The amount of the blood loss

Timepoint
The amount of the blood lost would be estimated 2 hours after the delivery (based on the difference of the weight of the tampon used). At the outset of the surgery, a tampon would be inserted into the vagina, the difference of its weight before the surgery and 2 hours after the surgery will be calculated.

Method of measurement
The amount of blood loss would be estimated through Gai et al.'s method:

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, with the help of an anesthesiologist, 20 minutes before the cesarean surgery 10 milligrams of Tranexamic acid for each kilogram of body mass combined with 200 milliliters of normal saline will be slowly injected within 5 minutes

Category
Treatment - Drugs

2

Description
Patients in the control group, will receive only 200

milliliters of normal saline within 5 minutes

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Dr. Ali Shariati

Full name of responsible person

Dr. Azin Alavi

Street address

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Dr. Azim Nejatizadeh

Street address

Hormozgan University of Medical Sciences-Research Council.

City

Bandar Abbas

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hormozgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shariati Hospital, Hormozgan University of Medical Sciences

Full name of responsible person

Azin Alavi

Position

Assistant Professor

Other areas of specialty/work

Street address

Shariati Hospital, Hormozgan University of Medical Sciences

City

Bandar Abbas

Postal code

Phone

+98 76 3333 2424

Fax

Email

azin_alavi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shariati hospital, Hormozgan University of Medical Sciences

Full name of responsible person

Azin Alavi

Position

Assistant Professor

Other areas of specialty/work

Street address

Shariati hospital, Hormozgan University of Medical Sciences

City

Bandar Abbas

Postal code

Phone

+98 76 3333 2424

Fax

Email

azin_alavi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shariati hospital, Hormozgan University of Medical Sciences

Full name of responsible person

Dr. Sara Moshfeghi

Position

Assistant Professor of Obstetrics and Gynecology.

Other areas of specialty/work

Street address

Shariati hospital, Hormozgan University of Medical Sciences

City

Bandar Abbas

Postal code

Phone

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty