Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effectiveness of the simultaneous use of Tranexamic acid and Oxytocin compared to the use of Oxytocin alone on the amount of bleeding after caesarean section .

Protocol summary

Study aim

Investigating the effectiveness of the simultaneous use of Tranexamic acid and Oxytocin compared to the use of Oxytocin alone in reducing the amount of bleeding after caesarean section in patient of Afzalipour Hospital in Kerman in 2023.

Design

Clinical trial with intervention and control groups, with parallel group design, double blind, randomized, phase 3, on 163 patients, Simple systematic division was used for randomization.

Settings and conduct

Place of study: Women's operating room of Afzalipour Hospital, Kerman. Study population: Selection of 163 candidates for elective or emergency caesarean section referred to Afzalipour Kerman Hospital in 1402 after checking the exclusion criteria. Type of blinding: double blind. How to blind: The researcher selects the patient's card and if the card is from the intervention group, informs the nurse to inject The Oxytocin and Tranexamic acid and if the patient is from the control group, only to inject it with Oxytocin. The doctor and the patient do not know which patient is from the intervention group and which one is from the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who referred to Afzalipour Kerman Hospital for elective or emergency caesarean section in 2023. Exclusion criteria: Patients with acreta and previa placentas; history of uterine atony; history of uterine rupture; history of coagulation disorders; history of myomectomy; Patients with chorioamnionitis; Patients with hematologic disorders.

Intervention groups

Control group: In the third stage of labor, only 30 units of Oxytocin are injected intramuscular(IM) by the nurse to 82 patients. Intervention group: In the third stage of labor; in addition to 30 units of Oxytocin (intramuscular), 1 g of Tranexamic acid is injected intravenously (IV) to 81 patients.

Main outcome variables

The amount of bleeding

General information

Reason for update

This study was conducted with a larger sample size.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230307057644N2**
Registration date: **2024-07-30, 1403/05/09**
Registration timing: **retrospective**

Last update: **2026-02-11, 1404/11/22**
Update count: **1**

Registration date

2024-07-30, 1403/05/09

Registrant information

Name

Ghazal Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 399 7804

Email address

mansori@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date
2023-05-22, 1402/03/01
Actual recruitment end date
2024-06-09, 1403/03/20
Trial completion date
2024-06-09, 1403/03/20

Scientific title
Investigating the effectiveness of the simultaneous use of Tranexamic acid and Oxytocin compared to the use of Oxytocin alone on the amount of bleeding after caesarean section .

Public title
Investigating the effect of Tranexamic acid in bleeding after caesarean section.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who referred to Afzalipour Kerman Hospital for elective or emergency caesarean section in 2023.
Exclusion criteria:
Patients with placenta Accreta and previa. Patients who have a history of uterine atony. Patients who have a history of uterine rupture. Patients who have a history of coagulation disorders. Patients with chorioamnionitis. Patients with hematologic disorders. Patients who have a history of myomectomy.
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **140**
Actual sample size reached: **163**
Randomization (investigator's opinion)
Randomized
Randomization description
We prepare some cards according to the sample size. On half of the cards we write intervention group and on the other half we write the control group. We put the cards in a basket. Then we randomly select them from the basket. After choosing each card, we number them in order and in the last stage according to the number of cards; we put them together. For example, card number 1 is the intervention group, card number 2 is the control group, card number 3 is the control group, etc. Then, without the patient or the doctor noticing, the researcher selects a card for each patient in the order we put and each patient is assigned to the intervention or control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double blind, the researcher selects the patient's card and if the card is from the intervention group, informs the nurse to inject The Oxytocin and Tranexamic acid and if the patient is from the control group, only to inject it with Oxytocin. The doctor and the patient do not know which patient is from the intervention group and which one is from the control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Medical University Campus, Kerman University of Medical Science, Haft-Bagh Highway, Kerman
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2023-02-28, 1401/12/09
Ethics committee reference number
IR.KMU.AH.REC.1401.290

Health conditions studied

1

Description of health condition studied
Postpartum hemorrhage
ICD-10 code
O72
ICD-10 code description
Postpartum hemorrhage

Primary outcomes

1

Description
The amount of bleeding
Timepoint
Measuring the patient's hemoglobin before delivery and 6 hour after delivery.
Method of measurement
Blood test for complete blood cells(CBC).

Secondary outcomes

1

Description
Requirement to blood transfusions (Packed cell) and blood products (Platelets and Fresh Frozen Plasma).
Timepoint
During delivery, 6 hours after delivery and one turn within the first 24 hours after delivery.
Method of measurement
Due to the volume of bleeding during delivery and the rate of decrease in hemoglobin in the blood test.

2

Description
Uterine atony
Timepoint
It is checked every 15 minutes in the first hour after delivery, every 30 minutes in the second hour after delivery, and then during the first 2 to 24 hours after delivery.
Method of measurement
Frequent examination of the uterine fundus.

3

Description
The need to use uterotonic drugs such as Methergin, Misoprostol, Factor 7, Prostaglandin.
Timepoint
During delivery and the first 24 hours after delivery
Method of measurement
According to the amount of bleeding, which medicine was used based on the opinion of the obstetrician and gynecologist.

4

Description
The need to use a Bakri Balloon
Timepoint
During delivery and the first 24 hours after delivery
Method of measurement
According to the amount of bleeding, a Bakri Balloon is inserted based on the opinion of the obstetrician and gynecologist.

5

Description
The need for surgery to remove the uterus (hysterectomy)
Timepoint
During delivery and the first 24 hours after delivery
Method of measurement
According to the amount of bleeding, hysterectomy is performed based on the opinion of the obstetrician and gynecologist.

Intervention groups

1

Description
Control group: In the third stage of labor, only 30 units of Oxytocin are injected intramuscular (IM) by the nurse to 82 patients included in the study.
Category
Treatment - Drugs

2

Description
Intervention group: In the third stage of labor; in addition to 30 units of Oxytocin (intramuscular), 1 g of Tranexamic acid is injected intravenously (IV) to 81 patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Ghazal Mansouri
Street address
Afzalipour Medical Education Center, next to Shahid Bahonar University, Imam Khomeini Highway
City
Kerman
Province
Kerman
Postal code
7616913355
Phone
+98 34 3132 8000
Email
mansori@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Reza Malekpour Afshar
Street address
University of Medical Sciences campus, at the beginning of Haft Bagh Alavi axis
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Province
Kerman
Postal code
7616913555

Phone
+98 34 3132 5700
Email
r_malekpoor@kmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Ghazal Mansouri
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
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Person responsible for scientific inquiries

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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
Ghazal Mansouri
Position
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Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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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
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
Total data
When the data will become available and for how

long

Starting from six months after the publication of the article.

To whom data/document is available

Researchers, students and doctors

Under which criteria data/document could be used

To conduct clinical trial

From where data/document is obtainable

Public or scientific responsible person

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

Send the proposal to the responsible persons email; mansori@kmu.ac.ir

Comments