Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of tranexamic acid with oxytocin in controlling bleeding due to uterine atony during cesarean section

Protocol summary

Study aim
The effect of tranexamic acid in controlling bleeding atonic uterus with oxytocin during cesarean section

Design
clinical trial with control group; With Parallel groups; Double blinded; randomized; design of 140 patients

Settings and conduct
Eligible patients entering the study referred to Imam Sajjad Hospital of Yasuj University of Medical Sciences will be divided into two groups of 70 people and the consequences of study will be measured.

Participants/Inclusion and exclusion criteria
Existence of uterine atony based on the surgeon's clinical judgment during the operation (bleeding has been more than 1000 cc and bleeding continues with the help of common methods such as uterine massage and oxytocine) No history of coagulation, kidney, liver disease No sensitivity to tranexamic acid No severe preeclampsia No thromboembolism No uncontrolled hypertension No history of heart attack or stroke No history of accreta and increta placenta No take anticoagulants 24 hours before surgery No take aspirin 7 days before surgery No consumption of omega 3 and garlic

Intervention groups
Intervention group: Oxytocin ampoule of 40 units per liter of ringer serum and tranxamic acid ampoule of 1 gram in 10 cc of normal saline serum are given slowly intravenously for 1 minute. Control group: receive 40 units of oxytocin per liter of ringer serum and 10 cc of normal saline slowly intravenously for 1 minute as a placebo.

Main outcome variables
Bleeding severity, the number of incoming cell pack, postoperative hemoglobin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200919048762N2**
Registration date: **2021-05-30, 1400/03/09**
Registration timing: **retrospective**

Last update: **2021-05-30, 1400/03/09**
Update count: **0**

Registration date
2021-05-30, 1400/03/09

Registrant information

Name
Parvin Ghaffari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 74 3100 1000

Email address
parvin.ghafari@yums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-03, 1399/10/14

Expected recruitment end date
2021-04-24, 1400/02/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of tranexamic acid with oxytocin in controlling bleeding due to uterine atony during cesarean section

Public title
Tranexamic acid and uterine atony
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Existence of uterine atony based on the surgeon's clinical judgment during the operation (bleeding has been more than 1000 cc and bleeding continues with the help of common methods such as uterine massage and oxytocine)
Exclusion criteria:
History of coagulation, kidney, liver disease Sensitivity to tranexamic acid Severe preeclampsia Thromboembolism Uncontrolled hypertension History of heart attack or stroke History of accreta and increta placenta Take anticoagulants 24 hours before surgery Take aspirin 7 days before surgery Consumption of omega 3 and garlic
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
The research population is randomly divided into two groups of intervention and control. Random assignment of patients to the two groups is a simple randomization using a sealed envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
Medications in both groups will be administered by an anesthesiologist without the knowledge of the research team, including gynecologist, data collector, and patient.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town, kohgiluyeh and boyer-ahmad
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7916839319
Approval date
2021-01-02, 1399/10/13
Ethics committee reference number
IR.YUMS.REC.1399.183

Health conditions studied

1

Description of health condition studied
uterine atony
ICD-10 code
O62.2
ICD-10 code description
Other uterine inertia

Primary outcomes

1

Description
Bleeding volume after atony
Timepoint
Immediatly after atony and after intervention
Method of measurement
Per cc and weight of used gazes

Secondary outcomes

1

Description
Hemoglobin's changes
Timepoint
6 hours after bleeding
Method of measurement
gr/dl with Spectrophotometer calibrated

2

Description
The need for blood products
Timepoint
After intervention until discharge
Method of measurement
based on unit and signs in surgen's examination or Hemoglobin less than 7

Intervention groups

1

Description
Intervention group: Oxytocin ampoule of 40 units per liter of ringer serum and tranxamic acid ampoule of 1 gram in 10 cc of normal saline serum are given slowly intravenously for 1 minute.
Category
Treatment - Drugs

2

Description
Control group: receive 40 units of oxytocin per liter of ringer serum and 10 cc of normal saline slowly intravenously for 1 minute as a placebo.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Yasuj Imam Sajjad Hospital
Full name of responsible person
Parvin Ghaffari
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Hossein Mari-Oriad
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad
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pari.ghaffari@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Parvin Ghaffari
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not 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
No - There is not 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