

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 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-Boyerahmad

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

Immediately 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

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No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

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+98 74 3100 1002

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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

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No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

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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

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

Contact

Name of organization / entity

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**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

Street address

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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