

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The role of tranexamic acid in management of uterine atony during delivery

#### Protocol summary

##### Summary

In this randomized clinical trial study, we investigated the effect of tranexamic acid in 90 patients, who were diagnosed as uterine atony by obstetrician following delivery (cesarean or vaginal) over 6 months period. The patients randomly allocated into two equal groups. In group 1 (n=45) received traditional treatment including oxytocin (30 IU oxytocin in 1 liter normal saline), metergine (0.2 mg IM), uterine massage, ice application, in group 2 (n=45), the patients received a single dose tranexamic acid (1gr), in 100 cc DW5%, IV, over 10 min., in addition to traditional treatment. The amount of blood loss, hemoglobin changes, need for surgical intervention, the need for blood products, duration of hospitalization, the two groups were compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013052613473N1**

Registration date: **2013-07-14, 1392/04/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-07-14, 1392/04/23

##### Registrant information

###### Name

Zoya Sadeghipour

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 1223 6374

##### Email address

zsadeghipour@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

institution

##### Expected recruitment start date

2012-04-20, 1391/02/01

##### Expected recruitment end date

2013-02-19, 1391/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The role of tranexamic acid in management of uterine atony during delivery

##### Public title

Tranexamic acid for treatment of postpartum hemorrhage

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: all women who were diagnosed as uterine atony by obstetrician following delivery;

exclusion criteria: history of any heart disease; liver disease; kidney disease; history of any hematologic or Thrombophlebitis disease;

Thromboembolism disease; and all women who received general anesthesia during delivery.

##### Age

No age limit

##### Gender

Female

##### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 90

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

"Qazvin University of Medical Science "

##### Street address

shahid bahonar bulvar

##### City

Qazvin

##### Postal code

##### Approval date

2013-05-27, 1392/03/06

##### Ethics committee reference number

28/20/7390

## 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

The need for surgical intervention.

#### Timepoint

Immediately after the intervention until discharge

#### Method of measurement

need to hypogastric Artery ligation, uterine artery ligation and hysterectomy based on Surgeon's visual judgment

### 2

#### Description

Bleeding volume after Atony

#### Timepoint

Immediately after Atony

#### Method of measurement

Per cc and counts gazes and long gazes, and the volume of blood in suction

### 3

#### Description

Hemoglobin's changes

#### Timepoint

6 and 24 hours after bleeding

#### Method of measurement

gr/dl with Spectrophotometer calibrated

### 4

#### 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

### 5

#### Description

Hospitalization

#### Timepoint

after delivery until discharge

#### Method of measurement

day

## Secondary outcomes

### 1

#### Description

nousa/vomiting/thromoamboli

#### Timepoint

after delivery until release

#### Method of measurement

examination

## Intervention groups

### 1

#### Description

In the intervention group after uterine Atony, in addition to receiving 30 units of oxytocin within 1 Liter saline, 0.2mg. Methergine IM, uterine massage and ice packs, 1gr trans examic acid, in the 100 cc 5% dextrose infusion within 10 minutes.

#### Category

Treatment - Drugs

## 2

### Description

In control group, after uterine atony only would be received (30 IU oxytocin in 1 liter of normal saline solution 0.2 mg IM ampoule Methergine and uterine massage and ice packs).

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kosar hospital

##### Full name of responsible person

zoya sadeghipour.MD

##### Street address

taleghani street

##### City

Qazvin

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

"Qazvin University of Medical Sciences"

##### Full name of responsible person

Mr Reza Ahmadian

##### Street address

shahid bahonar bulvar

##### City

Qazvin

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

"Qazvin 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

Qazvin medical university

##### Full name of responsible person

Zoya sadeghipour

##### Position

Residence of gynecology

##### Other areas of specialty/work

##### Street address

Kosar hospital-taleghani street

##### City

Qazvin

##### Postal code

##### Phone

+98 28 1223 6374

##### Fax

##### Email

zoya7s@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Qazvin medical university

##### Full name of responsible person

dr.Zoya sadeghipour

##### Position

residence of gynecology

##### Other areas of specialty/work

##### Street address

Kosar hospital-taleghani street

##### City

Tehran

##### Postal code

##### Phone

+98 21 4424 8439

##### Fax

##### Email

zoya7s@yahoo.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Qazvin medical university

##### Full name of responsible person

Ezat hajseid javadi

##### Position

gynecologist

##### Other areas of specialty/work

##### Street address

KOSar hospital-taleghani street

##### City

Qazvin

##### Postal code

##### Phone

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##### Fax

##### Email

Dr\_seidjavadi@yahoo.com

##### 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*