Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 group1(n=45) received traditional treatment including oxytocin(30 IU oxytocin in 1 litr.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

instution

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;liverdisease;kidney disease;history of any hematologic or Thrombophlebitis disease; Thromboembolism disease ;and all women who resieved 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

Immediatly 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,02mg. 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 recevied (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 universiyi
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
+98 28 1223 6374
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