

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

A comparison between the effect of tranexamic acid and placebo on the amount of hemorrhage in women following vaginal delivery and its adverse effects.

Protocol summary

Study aim

Effects of tranexamic acid on the amount of hemorrhage following vaginal delivery.

Design

double-blind placebo controlled randomized clinical trial on 200 women after vaginal delivery in Akbarabadi Hospital in Tehran..

Settings and conduct

200 women after vaginal delivery in Akbarabadi Hospital in Tehran..

Participants/Inclusion and exclusion criteria

women with a singleton pregnancy; gestational age between 37-42 weeks; normal blood pressure (< 140/90 mmHg) and informed consent for the study. Exclusion criteria: history of coagulopathy; pre-eclampsia; placental abruption; hypersensitivity to tranexamic acid; Body Mass Index(BMI) of more than 30; episiotomy and history of cardiac, hepatic, renal and neurologic disorders.

Intervention groups

Women in the intervention group received 10 mg/kg infusion of tranexamic acid in 100 mL normal saline and the control group received one vial of distilled water (as placebo) in 100 mL normal saline.

Main outcome variables

serum hemoglobin level; need of additional uterotonic agents; need of blood transfusion and surgery. Drug adverse effects were also evaluated in the two groups.

General information

Reason for update

Acronym

TXA and PPH

IRCT registration information

IRCT registration number: **IRCT20091023002624N22**
Registration date: **2017-12-20, 1396/09/29**

Registration timing: **retrospective**

Last update: **2017-12-20, 1396/09/29**

Update count: **0**

Registration date

2017-12-20, 1396/09/29

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 3487

Email address

maryamka@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2016-03-05, 1394/12/15

Expected recruitment end date

2017-06-09, 1396/03/19

Actual recruitment start date

2016-04-03, 1395/01/15

Actual recruitment end date

2017-04-21, 1396/02/01

Trial completion date

empty

Scientific title

A comparison between the effect of tranexamic acid and placebo on the amount of hemorrhage in women following vaginal delivery and its adverse effects.

Public title

Effect of tranexamic acid on postpartum hemorrhage.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant singleton gestational age between 37-42 weeks
normal blood pressure (< 140/90 mmHg) informed
consent for the study

Exclusion criteria:

history of coagulopathy pre-eclampsia placental
abruption hypersensitivity to tranexamic acid Body Mass
Index(BMI) of more than 30 episiotomy history of cardiac,
hepatic, renal and neurologic disorders

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Actual sample size reached: **207**

Randomization (investigator's opinion)

Randomized

Randomization description

simple, individual randomization using sealed envelopes.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, investigator and care providers(midwife)
were blinded to the study group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical
Sciences

Street address

Hemmat highway, Chamran Cross.

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2016-04-27, 1395/02/08

Ethics committee reference number

IR.IUMS.FMD.REC 1395.9211900010

Health conditions studied**1****Description of health condition studied**

hemorrhage following delivery

ICD-10 code

O72

ICD-10 code description

haemorrhage after delivery of fetus or infant

2**Description of health condition studied**

hemorrhage following delivery

ICD-10 code

O72.0

ICD-10 code description

Third-stage haemorrhage

3**Description of health condition studied**

hemorrhage following delivery

ICD-10 code

O75.9

ICD-10 code description

Complication of labour and delivery, unspecified

4**Description of health condition studied**

complications after delivery.

ICD-10 code

O75.8

ICD-10 code description

Other specified complications of labour and delivery

5**Description of health condition studied**

hemorrhage following delivery

ICD-10 code

O72.1

ICD-10 code description

Other immediate postpartum haemorrhage

Primary outcomes**1****Description**

hemoglobin level.

Timepoint

At the time of admission and 6 hours after delivery .

Method of measurement

blood test

Secondary outcomes**1****Description**

urine output

Timepoint

was checked at the beginning of labor and then during 6 hours after delivery ; every 15 minutes after labor for the first hour and then every 30 minutes for the second hour and finally every hour for another 4 hours.

Method of measurement

Data sheets, Monitoring of urine output

2**Description**

respiratory rate

Timepoint

was checked at the beginning of labor and then during 6 hours after delivery ; every 15 minutes after labor for the first hour and then every 30 minutes for the second hour and finally every hour for another 4 hours.

Method of measurement

Data sheets, Monitoring of respiratory rate

3**Description**

blood pressure

Timepoint

was checked at the beginning of labor and then during 6 hours after delivery ; every 15 minutes after labor for the first hour and then every 30 minutes for the second hour and finally every hour for another 4 hours.

Method of measurement

Data sheets, Monitoring of blood pressure

4**Description**

pulse rate

Timepoint

was checked at the beginning of labor and then during 6 hours after delivery ; every 15 minutes after labor for the first hour and then every 30 minutes for the second hour and finally every hour for another 4 hours.

Method of measurement

Data sheets, Monitoring of pulse rate

5**Description**

need of additional uterotonic agents .

Timepoint

Any time after delivery.

Method of measurement

Data sheets, using uterotonic agents.

6**Description**

need of blood transfusion.

Timepoint

Any time after delivery up to 24 hours.

Method of measurement

blood transfusion

7**Description**

need to surgical interventions.

Timepoint

Any time after delivery up to 24 hours.

Method of measurement

surgical interventions.

8**Description**

side effects of Tranexamic acid.

Timepoint

Any time after delivery up to 42 days.

Method of measurement

Data sheets

Intervention groups**1****Description**

Intervention group received 10 mg/kg intravenous TXA in 100 mL normal saline.

Category

Treatment - Drugs

2**Description**

Control group received one vial of distilled water (as placebo) in 100 mL normal saline.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Akbarabadi Teaching Hospital

Full name of responsible person

Maryam Kashanian

Street address

Molavi avenue, Molavi Cross Road.

City

Tehran

Province

Tehran

Postal code

۱۱۶۸۷۳۵۱۴

Phone

+98 21 5563 3244

Email

maryamkashanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Ali Javad Mousavi

Street address

Hemmat High way, Junction of Chamran Highway.

City

Tehran

Province

Tehran

Postal code

1۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

PR@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor.

Latest degree

Specialist

Other areas of specialty/work

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Molavi avenue, Molavi Cross Road.

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Phone

+98 21 5563 3244

Fax

Email

maryamkashanian@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Molavi avenue, Molavi Cross Road.

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Phone

+98 21 5563 3244

Fax

Email

maryamkashanian@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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City

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Province

Tehran

Postal code

۱۱۶۸۷۴۳۵۱۴

Phone

+98 21 5563 3244

Fax

Email

maryamkashanian@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available