

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effect of intravenous tranexamic acid on blood loss after vaginal delivery: A Randomized Controlled Trial

#### Protocol summary

##### Summary

This study is triple blind randomized controlled trial that will be carried out on 120 pregnant women. Subjects will be enrolled by using convenience sampling and randomly divided into two groups of 60 patients. After delivery of the anterior shoulder, subjects in the intervention group will receive 1g intravenous tranexamic acid in 200 ml normal saline over 10 minutes and the control group will receive 1g placebo. For measuring estimated blood loss, Blood collection container will be placed under the patient's bed. Also a plastic cover and drape will be spread under parturient woman immediately after neonate delivery. Differences between the weight of the full and empty container and the dry and bloody plastic cover, drapes and gauze pads will be recorded during the first two hours after delivery. Estimated blood loss will be measured by the method of Gai et al. Following delivery of the placenta, 10 units of oxytocin in 500 mL of normal saline will be infused intravenously to both groups and the duration of the third stage of labor, neonate and placental weight will be recorded. Complications resulting from injection of tranexamic acid and vital signs will be monitored during the first two hours after delivery. Before and 12-24 hours after delivery, the level of hemoglobin and hematocrit of subjects will be measured. Calculated blood loss will be assessed according to pre- and post delivery hematocrit. SPSS software will be used for data analysis and independent t-test, ANCOVA, Ki-square test will be used. Following delivery of the placenta, 10 units of oxytocin in 500 mL of normal saline will be infused intravenously to both groups and the duration of the third stage of labor, neonate and placental weight will be recorded. Complications resulting from injection of tranexamic acid and vital signs will be monitored during the first two hours after delivery. Before and 12-24 hours after delivery, the level of hemoglobin and hematocrit of subjects will be measured. Calculated blood loss will be assessed according to pre- and post delivery hematocrit.

SPSS software will be used for data analysis and independent t-test, ANCOVA, Ki-square test will be used.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012072910324N2**

Registration date: **2012-08-09, 1391/05/19**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-08-09, 1391/05/19

##### Registrant information

##### Name

Mojgan Mirghafourvand

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6969

##### Email address

mirghafourvandm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

##### Expected recruitment start date

2012-08-15, 1391/05/25

##### Expected recruitment end date

2012-10-30, 1391/08/09

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of intravenous tranexamic acid on blood loss after vaginal delivery: A Randomized Controlled Trial

**Public title**

The effect of intravenous tranexamic acid on blood loss after vaginal delivery

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: -Women with singleton pregnancy between 38 to 42 weeks - Cephalic presentation - No history of cesarean section or uterine surgery - No history of uterine myoma - Normal blood pressure - No history of postpartum haemorrhage - No history of coagulation disorders - No history of heart disease - No history of renal disease - No history of blood disorders and anemia - No history of cerebrovascular disease - Absence of diabetes and preeclampsia in pregnancy current - Absence of polyhydramnios of macrosomia in the current pregnancy - lack of long-term induction of labor in first stage Exclusion criteria: - Instrumental delivery - Extensive vaginal and cervical lacerations - Need for placenta curettage - Continuous pressure in the fundus of the uterus before the fetus and placenta expulsion.

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Tabriz University of Medical Sciences Ethics Committee

**Street address**

Tabriz-Golgasht street-Tabriz University of Medical Sciences-Building 2 - Floor 3

**City**

Tabriz

**Postal code****Approval date**

2012-06-13, 1391/03/24

**Ethics committee reference number**

9168

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

postpartum haemorrhage

**ICD-10 code**

O72.1

**ICD-10 code description**

Other immediate postpartum haemorrhage

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

comparison of measured blood loss after delivery in the intervention group (receiving tranexamic acid and oxytocin) and control group ( receiving placebo of tranexamic acid and oxytocin)

**Timepoint**

first two hours after delivery

**Method of measurement**

Differences between the weight of the full and empty container and the dry and bloody plastic cover, drapes and quaze pads will be recorded during the first two hours after delivery and blood loss will be assessed by the method of Gai et al.

**2****Description**

Comparison of the calculated blood loss after delivery in the intervention group (receiving tranexamic acid and oxytocin) and control group ( receiving placebo tranexamic acid and oxytocin)

**Timepoint**

Before and 12-24 hours after delivery

**Method of measurement**

Calculated blood loss will be assessed according to pre- and post delivery hematocrit

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

Comparison of postdelivery hematocrit with effect

control of predelivery hematocrit between intervention group (receiving tranexamic acid and oxytocin) and control group (receiving placebo of tranexamic acid and oxytocin)

**Timepoint**

Before and 12-24 hours after delivery

**Method of measurement**

hematocrit assessment

**2**

**Description**

Comparison of postdelivery Hemoglobin with effect control of predelivery Hemoglobin between intervention group (receiving tranexamic acid and oxytocin) and control group (receiving placebo of tranexamic acid and oxytocin)

**Timepoint**

Before and 12-24 hours after delivery

**Method of measurement**

Hemoglobin assessment

**3**

**Description**

Comparison of the mean duration of the third stage of labor between intervention group (receiving tranexamic acid and oxytocin) and control group (receiving placebo of tranexamic acid and oxytocin)

**Timepoint**

From newborn delivery to exclusion of the placenta

**Method of measurement**

Check of the time in second

**4**

**Description**

Comparison of need for additional uterotonic medication after delivery between intervention group (receiving tranexamic acid and oxytocin) and control group (receiving placebo of tranexamic acid and oxytocin)

**Timepoint**

30, 45, 60, 90 and 120 minute after delivery

**Method of measurement**

Checklist

**5**

**Description**

Comparison of vital signs between intervention group (receiving tranexamic acid and oxytocin) and control group (receiving placebo of tranexamic acid and oxytocin)

**Timepoint**

15-30-45-60-90 and 120 minutes after delivery

**Method of measurement**

checklist

**Intervention groups**

**1**

**Description**

Intervention group: After delivery of anterior shoulder, 1g tranexamic acid in 200 ml normal saline will be infused intravenously over 10 minutes.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: After delivery of anterior shoulder, 1g placebo of tranexamic acid in 200 ml normal saline will be infused intravenously over 10 minutes.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Alzahra Educational and Treatment Center, Tabriz

**Full name of responsible person**

Mina shirdel

**Street address**

Tabriz-South Artesh street, Alzahra Educational and Treatment Center

**City**

Tabriz

**2**

**Recruitment center**

**Name of recruitment center**

Taleghany Educational and Treatment Center, Tabriz

**Full name of responsible person**

Mina Shirdel

**Street address**

Tabriz, Rah Ahan street

**City**

Tabriz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Womens Reproductive Health Research center, Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Fatemeh Abasalizade

**Street address**

South Artesh Ave., Alzahra educational and treatment center

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Womens Reproductive Health Research center, Tabriz  
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**

Tabriz University of Medical Sciences, Nursing &  
Midwifery Faculty

**Full name of responsible person**

Dr.Mojgan Mirghafourvand

**Position**

PhD of Reproductive Health/ Assistant Professor

**Other areas of specialty/work****Street address**

Tabriz Nursing & midwifery Faculty , South Shariaty

**City**

Tabriz

**Postal code**

51745-347

**Phone**

+98 41 1479 6770

**Fax**

+98 47 96969

**Email**

Mirghafourvandm@tbzmed.ac.ir,  
Mirg1385@yahoo.com

**Web page address**

<http://nursing.tbzmed.ac.ir/>

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences, Nursing &  
Midwifery Faculty

**Full name of responsible person**

Dr. Mojgan Mirghafourvand

**Position**

PhD of Reproductive Health/ Assistant Professor

**Other areas of specialty/work****Street address**

Tabriz Nursing & midwifery Faculty , South Shariaty

**City**

Tabriz

**Postal code**

51745-347

**Phone**

+98 41 1479 6770

**Fax**

+98 47 96969

**Email**

Mirghafourvandm@tbzmed.ac.ir

**Web page address**

<http://nursing.tbzmed.ac.ir>

**Person responsible for updating data****Contact****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*