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 over10 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 quaze 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.

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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)

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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 polyhydramnious 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 curettag - 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

Comparsion 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 120minutes after delivery

Method of measurement

cheklist

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
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Full name of responsible person
Dr.Mojgan Mirghafourvand
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Other areas of specialty/work
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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