# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Clinical trial of the effect of topical tranexamic acid on the amount of episiotomy bleeding in primigravida women and comparison with the control group

## Protocol summary

**Study aim**

In relation to postpartum bleeding, extensive studies have been conducted on the positive effect of tranexamic acid in reducing post-partum bleeding, its administration time, and effective dose, but its local effect on episiotomy bleeding in vaginal deliveries has not been investigated and the purpose of this study is to investigate this issue.

**Design**

A clinical trial with a control group, with parallel groups, one-sided blind, randomized, 162 patients. The software was used for randomization.

**Settings and conduct**

place: Akbarabadi hospital maternity ward Immediately after the removal of the placenta, Trenexamic or normal saline solution will be poured locally on the episiotomy site. Take the solution freely without the interference of sterile gas and similar We pour it on the site and wait for a minute (the medicine is not injected on the site. The patient and the analyzer are blind.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: All vaginal births over 34 weeks in primiparous women who are candidates for episiotomy exclusion criteria: Lack of consent to participate in the study Patients with known coagulopathy History of previous perineal surgery Patients with uterine atony retained placenta Instrumental delivery Simultaneous rupture of the cervix Receiving venous tranexamic acid

**Intervention groups**

In the intervention group, 1 gram of Trenoxamic acid with 20 cc of normal saline is poured at the episiotomy site. In the control group, 20 cc of normal saline is poured into the episiotomy site.

**Main outcome variables**

Hemoglobin and hematocrit changes, the need to receive blood, the duration of hospitalization, the rate of wound opening and the rate of wound infection, and the rate of thromboembolic events.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180409039247N4**
Registration date: **2023-02-23, 1401/12/04**
Registration timing: **prospective**

Last update: **2023-02-23, 1401/12/04**
Update count: **0**

**Registration date**

2023-02-23, 1401/12/04

**Registrant information**

**Name**

Marjan Ghaemibidgoli

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 8800 4858

**Email address**

m_ghaemi@razi.tums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-04-05, 1402/01/16

**Expected recruitment end date**

2023-10-08, 1402/07/16

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Clinical trial of the effect of topical tranexamic acid on the amount of episiotomy bleeding in primigravida women and comparison with the control group

**Public title**
The effect of topical tranexamic acid on the episiotomy bleeding, a clinical trial
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
vagina delivery beyond 34 weeks primiparity candidates for episiotomy
**Exclusion criteria:**
Lack of consent to participate in the study known coagulopathy history of previous perineal surgery uterine atony retained placenta delivery with instruments Cervical rupture at the same time receiving spontaneous tranexamic acid
**Age**
From **18 years** old to **45 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**

- Participant
- Data analyser

**Sample size**
Target sample size: **162**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
A computerized randomization list, generated by an independent statistician blinded to the trial and unrelated to the subjects involved, will use 1:1 allocation. All participants are blinded to the list. The randomization list will be administered using identical, sequentially numbered containers of study medication. These containers will be labeled identically by two investigators who will not be involved in recruiting study subjects. The block random allocation method was designed by an epidemiologist using WWW.Sealedenvelop.com. The blocks will be 2 alleles of size 6. The random assignment list is AAABBB-AABBAB-ABBBAA-AABABB-...., in this sequence A is transgenic and B is controlled.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
A single blind study in which the patient and the analyst are blinded. In the consent form, the patient is aware of the two study groups, but does not know whether he is in the intervention group or the control group. The researcher is not blind because he supervises the episiotomy process and uses the medicine. The nurse is not blind because the doctor prescribes the medicine. The information in the forms and the evaluation table are marked with codes that the analyst is blind to and does not know the type of division.
**Placebo**
Not used
**Assignment**
Single
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Iran university of Medical Sciences
**Street address**
Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
۱۴۴۹۶۱۴۵۳۵
**Approval date**
2023-01-21, 1401/11/01
**Ethics committee reference number**
IR.IUMS.REC.1401.837

## Health conditions studied

### 1

**Description of health condition studied**
Episiotomy bleeding rate
**ICD-10 code**
O72
**ICD-10 code description**
Postpartum hemorrhage

## Primary outcomes

### 1

**Description**
The primary outcomes is changes in hemoglobin and hematocrit, the need for blood transfusion, the duration of hospitalization
**Timepoint**
Hemoglobin and hematocrit check before admission and 12 hours later and also to check complications 1 week after discharge.
**Method of measurement**
Hemoglobin and hematocrit check with blood test (cbc) and check the need for transfusion, discharge time, possible wound opening and thromboembolic events based on history

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Tranexamic acid mixed with 20 cc of normal saline pored in episiotomy site.
**Category**
Prevention

### 2

**Description**
Control group: 20 cc of normal saline pored in episiotomy site.
**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Akbarabadi hospital
**Full name of responsible person**
Maliheh Fakehi
**Street address**
Baghefrdos station, Moulavi Street
**City**
Tehran
**Province**
Tehran
**Postal code**
1168743514
**Phone**
+98 21 5560 6034
**Email**
akbarabadihosp@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Maliheh Fakehi
**Street address**
Bagheferdos station, Moulavi Street
**City**
Tehran
**Province**
Tehran
**Postal code**
1168743514
**Phone**
+98 21 5560 6034
**Email**
maryam.fakehi@gmail.com
**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 Fakehi
**Position**
Assisted professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Gynecology and Obstetrics
**Street address**
Bagheferdos station, Moulavi Street
**City**
Tehran
**Province**
Tehran
**Postal code**
1168743514
**Phone**
+98 21 5560 6034
**Email**
marjan_ghaemi@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Marjan Ghaemibidgoli
**Position**
Assissted professor
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Gynecology and Obstetrics

**Street address**
Emam khomeini hospital
**City**
Tehran
**Province**
Tehran
**Postal code**
14146
**Phone**
+98 21 8800 4858
**Fax**
**Email**
marjan_ghaemi@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Marjan
**Position**
Assissted professor
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Gynecology and Obstetrics
**Street address**
No. 25 Naz Alley, Babataher St
**City**
Tehran
**Province**
Tehran
**Postal code**
14146
**Phone**
+98 21 8800 4858
**Fax**
**Email**
marjan_ghaemi@yahoo.com

## 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**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available