Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
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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
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Person responsible for updating data

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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