Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

A placebo-controlled clinical trial to assess efficacy of tranexamic acid in reducing hemorrhage after vaginal delivery

Protocol summary

Summary

To assess the efficacy of Tranexamic acid in reducing hemorrhage after vaginal delivery, a randomized, placebo- controlled clinical trial of 200 women with term, singleton pregnancy candidate for the first normal vaginal delivery is designed. Other inclusion criteria are no history of severe medical complications, thrombotic events, allergy to tranexamic acid, preeclampsia and visual problem. Exclusion criteria are patient avoidance and placenta abruption. Patients will be randomized with Block randomization method into two groups, after approval and inclusion criteria assessment. In the first group (experimental group) 1 gram of Tranexamic acid diluted in 20 ml dextrose 5% and in the second group (experimental group), 20 ml dextrose 5% and placebo(10 ml normal saline) will be administered soon after delivery. Hemoglobin level will be measured promptly at the time of admission and also 24 hours after delivery. The primary outcome is hemoglobin decline more than 10% (considered as postpartum hemorrhage). Blood pressure and pulse rate will be checked 1 hour and 2 hours after delivery. The studied parturient will be evaluated 24 hours after delivery in terms of drug induced complications and thrombotic events. Maternal outcomes such as need to transfusion, surgery, hysterectomy and death will be documented .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204079399N1**
Registration date: **2012-11-15, 1391/08/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-11-15, 1391/08/25

Registrant information

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Fereshteh Heidari Shirazi
Name of organization / entity
kashan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2012-11-10, 1391/08/20

Expected recruitment end date

2013-01-09, 1391/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A placebo-controlled clinical trial to assess efficacy of tranexamic acid in reducing hemorrhage after vaginal delivery

Public title

A placebo-controlled clinical trial to assess efficacy of tranexamic acid in reducing hemorrhage after vaginal delivery

Purpose

Prevention

Inclusion/Exclusion criteria

1- inclusion criteria: - women with term, singleton pregnancy candidate for the first vaginal delivery -No history of sever medical complications involving the heart,brain ,kidney - No history of allergy to tranexamic acid -No history of visual problem -No history of sever pregnancy complications such as preeclampsia -No history of thromboembolic events 2- exclusion criteria: - patient avoidance -placenta abruption

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Kashan University of Medical Sciences 5th km of ghotberavandi blvd. Kashan Iran

City
Kashan

Postal code
87155/111

Approval date
2012-01-30, 1390/11/10

Ethics committee reference number
29/5/1/3603/پ

Health conditions studied

1

Description of health condition studied
postpartum hemorrhage

ICD-10 code
072.1

ICD-10 code description
Haemorrhage following delivery of placenta

Primary outcomes

1

Description
hemoglobin

Timepoint
Before and 24 hours after delivery

Method of measurement
laboratory

2

Description
maternal death

Timepoint
During 24 hours after delivery

Method of measurement
outcome form

Secondary outcomes

1

Description
Blood transfusion

Timepoint
24 hours after delivery

Method of measurement
outcome form

2

Description
thromboembolic events in mother

Timepoint
24 hours after delivery

Method of measurement
physical exam

3

Description
Surgical intervention

Timepoint
24 hours after delivery

Method of measurement
outcome form

Intervention groups

1

Description
In the experimental group , 1gram of tranexamic acid diluted in 20ml Dextrose 5% will be administered intravenously soon after neonatal delivery. Blood pressure, pulse rate will be checked, 1 hour and 2 hours

after delivery. Hemoglobin levels will be measured promptly at the time of admission and also 24 hours after delivery.The studied parturients will be evaluated 24 hours after normal vaginal delivery in terms of drug induced complications . Maternal outcomes such as need to transfusion , surgery ,hysterectomy or death if occur will be documented .

Category

Prevention

2

Description

In the control group , 20ml Dextrose 5% and placebo(normal saline) will be administered intravenously soon after neonatal delivery. Blood pressure, pulse rate will be checked, 1 hour and 2 hours after delivery.Hemoglobin levels will be measured promptly at the time of admission and also 24 hours after delivery. The studied parturients will be evaluated 24 hours after normal vaginal delivery in terms of drug induced complications . Maternal outcomes such as need to transfusion , surgery ,hysterectomy or death if occur will be documented .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr.Fereshteh Heidari Shirazi

Street address

Shahid Beheshti Hospital 5th km of Ghotberavandi blvd. Kashan Iran

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research ,Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Hamidi

Street address

Kashan University of Medical Sciences 5th km of Ghotberavandi blvd. kashan iran

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research ,Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Dr.Fereshteh Heidari Shirazi

Position

Member of research committee

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Gynecologist

Other areas of specialty/work

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Other areas of specialty/work
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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