Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Assessment of effect of intravenus tranexamic acid on hemorrhage reduction during and after hysteretomy in comparison with control group

Protocol summary

Study aim
Effectiveness of Tranexamic Acid in reducing bleeding and blood transfusion in hystrectomy.

Design
Randomized, blinded, controlled clinical trial with a parallel-group design of 60 patients

Settings and conduct
This study was done in Shahid Beheshti Hospital in Isfahan in years 2016-2017.Tranexamic acid injection was prepared by diluting1 gr (10 mL) tranexamic acid with 20 mL of 5% glucose and it was injected 20 min before the incision. If patients had sign of hemodynamic instability due to blood loss (heart rate >120 beats/min or a systolic blood pressure decrease by more than 20% of base value) despite adequate volume replacement, blood transfusion was given. All patients' preoperative and 12th hour postoperative blood samples were analyzed for hemoglobin, hematocrit,platelet count,INR,prothrombin time (PT), activated partial thromboplastin time (aPTT). The study was double-blinded with the patient and caregiver(surgeon and anesthesiologist). they were not aware of the treatment of the groups.

Participants/Inclusion and exclusion criteria
Female patients of 35 to 70 years; American society of anesthesiologists (ASA) physical status class I and II; scheduled for either vaginal or abdominal hysterectomy,were enrolled for the study. Exclusion criterion were allergy to tranexamicacid; anemia; preoperative hepatic or renal dysfunction; serious cardiac or respiratory disease; ASA phisycal status morer than 2; congenital or acquired coagulopathy or a history of deep vein thrombosis or thromboembolic disease.

Intervention groups
This study investigated the effect of tranexamicacid on control of bleeding and the need for transfusion in case and control groups.

Main outcome variables
bloodloss; blood transfusion؛ hemoglobin level ؛operation time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210703051769N1**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **retrospective**

Last update: **2021-08-22, 1400/05/31**
Update count: **0**

Registration date
2021-08-22, 1400/05/31

Registrant information

Name
Ensiyeh Bahadoran

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 28 3333 0923

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bahadoran.ensiyeh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-08-22, 1395/06/01

Expected recruitment end date
2018-03-20, 1396/12/29

Actual recruitment start date
2016-09-22, 1395/07/01

Actual recruitment end date
2018-01-20, 1396/10/30

Trial completion date

2018-01-21, 1396/11/01

Scientific title
Assessment of effect of intravenus tranexamic acid on hemorrhage reduction during and after hysteretomy in comparison with control group

Public title
Assessment of effect of Tranexamic acid on hemorrhage reduction in hysterectomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate of vaginal or abdominal hystrectomy Between 35-70 years old American society of anesthesiologist (ASA) grade for physical status 1 or 2

Exclusion criteria:
Anemia Hepatic dysfunction Renal dysfunction Serious cardiac disease Serious respiratory disease Acquired or congenital coagulopathy Previous history of deep venus thrombosis or thromboembolic disease ASA more than 2 Sensitive to tranexamicacid

Age
From **35 years** old to **70 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
With Random allocation software patients got numbers from 1 to 60.If the paitient had even numder it has entered to T group and if the patient had odd numder it has entered to S group.Group T recieved 1 gr tranexamic acid,in the other hand group S recieved the same amount of normal saline.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, clinical caregiver and patients participating in the study were blind. All patients were aware of the benefits and the adverse effects of clinical trial, but they were unaware about who received the intervention. Clinical caregiver, surgeon and anesthesiologist were blind. Tranexamic acid was administered 20 minutes before the surgery by an anesthesiologist.Some of them received placebo (normal saline solution).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Hezar Jerib street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2017-07-02, 1396/04/11

Ethics committee reference number
IR.MUI.REC.1396.3.201

Health conditions studied

1

Description of health condition studied
Hysterectomy

ICD-10 code
Z90.710

ICD-10 code description
Acquired absence of both cervix and uterus

2

Description of health condition studied
Blood transfusion

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Tranexamic acid

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
blood loss

Timepoint
During and after sugery

Method of measurement
During the surgery by weighting swabs,spinges,operative drapes and measuring the volume in suction buttles after surgery by measuring the drain collectors in post

anesthesia care unit.

2

Description
Blood transfusion
Timepoint
During and 12 hours after surgery
Method of measurement
Pack cell

Secondary outcomes

1

Description
Hemoglobin
Timepoint
During and 12 hours after surgery
Method of measurement
Blood test

2

Description
Hematocrit
Timepoint
Before and 12 hours after surgery
Method of measurement
Blood test

3

Description
Operation time
Timepoint
Operation time
Method of measurement
Timer

Intervention groups

1

Description
Intervention group: recieve 1 gr tranexamic acid as slow intravenus bolus.Tranexamic injection was prepared by diluting 1 gr (10ml) tranexamic acid with 20 ml of5% glucose.
Category
Treatment - Drugs

2

Description
Control group: recieve equal volume of normal saline (10ml).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital
Full name of responsible person
Ensiyeh Bahadoran
Street address
West Motahari Street,Felezi Bridge
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Qazvin University of Medical Sciences
Full name of responsible person
Ensiyeh Bahadoran
Position
Medical doctor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared after unidentifiable individuals.
When the data will become available and for how long
6 month after publication,data will be accessible.
To whom data/document is available
The study will be available for researchers who work in academic and scientific institutions.
Under which criteria data/document could be used
Due to the unrecognizable people,no restriction will apply.
From where data/document is obtainable
Ensiyeh bahadoran ; Phone number:0098 9127689597 ;Email:bahadoran.ensiyeh@yahoo.com
What processes are involved for a request to access data/document
Data will be provided in 1-2 weeks.
Comments