

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of preoperative intravenous tranexamic acid administration on the amount of blood loss in women underwent hysterectomy

Protocol summary

Summary

The objective of this study is to determine the effect of preoperative tranexamic acid administration on amount of blood loss during hysterectomy . This study, clinical trials, double-blind, placebo- control, single center are conducted in Arash women's hospital. Among women underwent hysterectomy 106 patient are entered in this study and randomly divided in two groups (by block randomization). Inclusion criteria: Uterine size <14 cm, hysterectomy for benign pathology, uterine prolapsed and abnormal uterine bleeding. Exclusion criteria: History of previous myomectomy, coagulation disorder , history of abnormal coagulation test, thrombophilie, coagulopathy, cardiovascular, tromboemboli and ceasar, renal and liver dysfunction and patients with an allergy to tranexamic acid and BMI>30. Ten minute before surgery 10mg/kg tranexamic acid with 200 cc normal saline is injected Intravenously for intervention group. In control group 200 cc normal saline is administrated . Before and after surgery all of the surgery bands are weighted and the blood volume in suction devise is recorded . six and twenty four hours after hysterectomy, the hemoglobin will checked. Patients are checked for side effects of tranexamic acid (ceasar, peripheral vascular thrombosis, dizziness). All drugs are prepared by anesthesia technisian and patients are divided in two groups by a person who is not a member of the research group and members of this do not known about the kind of drugs .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306181951N3**

Registration date: **2013-07-28, 1392/05/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-28, 1392/05/06

Registrant information

Name

Nasrin Faridi Tazeh-kand

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 3283

Email address

nfaridi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preoperative intravenous tranexamic acid administration on the amount of blood loss in women underwent hysterectomy

Public title

The effect of preoperative tranexamic acid administration on the amount of blood loss during hysterectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Uterine size <14 cm, hysterectomy for benign pathology, uterine prolapsed and abnormal uterine bleeding. Exclusion criteria: History of previous myomectomy, coagulation disorder, history of abnormal coagulation test, thrombophilia, coagulopathy, cardiovascular, thromboemboli and cesar, renal and liver dysfunction and patients with an allergy to tranexamic acid and BMI>30.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

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

Tehran University of Medical Sciences

Street address

Qods St, Keshavarz Blv

City

Tehran

Postal code

Approval date

2013-07-20, 1392/04/29

Ethics committee reference number

92-01-39-22126-89720

Health conditions studied

1

Description of health condition studied

blood loss during surgery

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

The amount of blood loss

Timepoint

Before surgery

Method of measurement

Before and after surgery all of the surgery bands are weighted and the blood volume in suction devise is recorded

2

Description

Side effects of tranexamic acid

Timepoint

During and after surgery

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ten minute before surgery 10mg/kg tranexamic acid with 200 cc normal saline is injected Intravenously.

Category

Treatment - Drugs

2

Description

The control group: Ten minute before surgery 200 cc normal saline is administrated.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Hospital

Full name of responsible person

Nasrin Faridi Tazeh-kand

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences , Deputy of Research

Full name of responsible person

D.r Akbar Fotohi

Street address

Qods St, Keshavarz Blvd

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences , Deputy of Research

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

Arash Women 's Hospital , Tehran University of Medical Sciences

Full name of responsible person

Nasrin Faridi Tazeh-kand

Position

Assistant professor

Other areas of specialty/work**Street address**

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse,Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 7771 9922

Fax**Email**

nfaridi@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arash Women 's Hospital , Tehran University of Medical Sciences

Full name of responsible person

Dr Nasrin Faridi Tazeh-kand

Position

Assistant professor

Other areas of specialty/work**Street address**

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse,Tehran,Iran

City

Tehran

Postal code**Phone**

+98 21 7771 9922

Fax**Email**

nfaridi@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arash Women 's Hospital , Tehran University of Medical Sciences

Full name of responsible person

Ladan Hosseini

Position

MS , Employee of research development center

Other areas of specialty/work**Street address**

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse,Tehran.Iran

City

Tehran

Postal code**Phone**

+98 21 7771 9922

Fax**Email**

hosseiniladan@yahoo.com

Web page address

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