

# 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, thrombophilie, coagulopathy, cardiovascular, tromboemboli and ceasar, 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**

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## Person responsible for scientific inquiries

#### Contact

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Arash Women 's Hospital , Tehran University of Medical Sciences

**Full name of responsible person**

Dr Nasrin Faridi Tazeh-kand

**Position**

Assistant professor

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## 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

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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*