

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of the effects of Tranexamic Acid and Vitamin K in the prevention of hemorrhage in TURP surgery.

#### Protocol summary

##### Study aim

Determining the Effect of Transxamic Acid and Vitamin K in Preventing Bleeding in TURP Surgery

##### Design

Patients are divided into three groups of 25 people. The first group was given placebo (normal saline), the second group (tranexamic acid) and the third group were given vitamin K Clinical study of a randomized parallel, One-sided blind

##### Settings and conduct

Patients are divided into three groups of 25 people. The first group was given placebo (normal saline), the second group (tranexamic acid) and the third group were given vitamin K. The study is conducted at Khatam Al-Anbiya Hospital in Shahrood. Participants in the study are blind

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Male gender, age 60 to 90 years, satisfaction with conducting prostatectomy through the duct Exclusion criteria include coagulation disorder (hemophilia, VWD, ITP, factor 5 deficiency), liver disease (cirrhosis, hepatitis, liver cancer), anticoagulant drugs (warfarin, heparin, enoxaparin, plavix), heart patients (history of MI Last year, Class 3 and 4heart failure , and arrhythmia such as AF), history of stroke, thrombotic disease, age less than 60 years of nonprostatic action, and dissatisfaction with participating in the study

##### Intervention groups

Patients are divided into three groups of 25 people. The first group was given placebo (normal saline), the second group (tranexamic acid) and the third group were given vitamin K

##### Main outcome variables

The incidence of hematuria, reduction in hemoglobin levels, changes in blood pressure

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20181031041515N1**

Registration date: **2019-06-01, 1398/03/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-01, 1398/03/11**

Update count: **0**

##### Registration date

2019-06-01, 1398/03/11

#### Registrant information

##### Name

Milad Talezari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3522 2576

##### Email address

milad.tale72@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

##### Expected recruitment start date

2018-11-06, 1397/08/15

##### Expected recruitment end date

2019-07-06, 1398/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Comparison of the effects of Tranexamic Acid and Vitamin K in the prevention of hemorrhage in TURP surgery.

## Public title

The Effects of Tranexamic Acid and Vitamin K in the prevention of hemorrhage in TURP surgery.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Male gender 60 to 90 year-old Satisfaction for performing TURP surgery

### Exclusion criteria:

Coagulation disorders (hemophilia and ...) Liver Disease (Cirrhosis and ...) Uses of anticoagulant medication (Warfarin and Heparin and Plavix) History of heart disease History of thrombotic stroke

## Age

From **60 years** old to **90 years** old

## Gender

Male

## Phase

2-3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **75**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The computerized block randomization (block sizes of 3 and 9) will be carried out in this study. An independent clinical epidemiologist, who will not be involved in the conduct of the study used a computerized block randomization program (STATA14 software) to produce the allocation codes. The randomization sequences will be concealed in lightproof, sealed envelopes. The research assistant opened sealed, numbered, opaque envelopes containing allocation codes. The eligible participants will be randomized to three equal groups (normal saline group, tranexamic acid group and vitamin K group) according to the randomization list after signing informed consent form.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients will not be aware of the type of medication they receive and the second executor of the research project will complete the questionnaire at the end of the treatment without knowledge of the three groups. Also the data will be analyzed without any information about group selection

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee on Biomedical Research of the Islamic Azad University of Shahrood Branch

##### Street address

Islamic Azad University of Shahrood Branch, Blvd university, Shahrood Town

##### City

Shahrood

##### Province

Semnan

##### Postal code

3619943189

#### Approval date

2018-09-29, 1397/07/07

#### Ethics committee reference number

IR.IAU.SHAHROOD.REC.1397.009

## Health conditions studied

### 1

#### Description of health condition studied

Benign prostate Hyperplasia

#### ICD-10 code

N40

#### ICD-10 code description

Enlarged prostate

## Primary outcomes

### 1

#### Description

Bleeding status after TURP surgery

#### Timepoint

Within 48 hours after surgery

#### Method of measurement

Volume of fluid in the urethra for hematuria, the amount of hemoglobin before and after surgery

## Secondary outcomes

### 1

#### Description

The amount of bleeding during and after the TURP operation

#### Timepoint

During and after the TURP operation

#### Method of measurement

Hemoglobin level and serum volume of used washing

## Intervention groups

## 1

### Description

Intervention group: Ampol of 1 vial of Transamin 500 mg (Caspian Company Rasht Drug) will be injected into the serum during an operation in the Tranexamic Acid group.

### Category

Treatment - Drugs

## 2

### Description

Intervention group: Vitamin K ampol with dosage 10 mg (Osvah Pharmaceutical company) will be injected intramuscularly in the vitamin K group 8 hours prior to surgery.

### Category

Treatment - Drugs

## 3

### Description

Control group: The normal serum saline (Tehran Pharmacy Company) will be administered to the control group during surgery.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Khatam Al-Anbiya Hospital in Shahrood

#### Full name of responsible person

Milad Talezari

#### Street address

No.45 , First Alley, Mofateh St , Station St

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Shahrood

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3616643417

#### Phone

+98 23 3224 2487

#### Email

milad.tale72@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Sahebali Monafi

#### Street address

University Blvd - Shahrud Islamic Azad University

#### City

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#### Phone

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shahrood.azad.university@gmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Islamic Azad University

### 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

Islamic Azad University

#### Full name of responsible person

Yousef Kolookhi

#### Position

Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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Yousef Kolookhi

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Professor  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Milad Talezari  
**Position**  
Medical student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
General Practitioner  
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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**  
Undecided - It is not yet known if there will be a plan to make this available  
**Statistical Analysis Plan**  
Undecided - It is not yet known if there will be a plan to make this available  
**Informed Consent Form**  
Undecided - It is not yet known if there will be a plan to make this available  
**Clinical Study Report**  
Undecided - It is not yet known if there will be a plan to make this available  
**Analytic Code**  
Undecided - It is not yet known if there will be a plan to make this available  
**Data Dictionary**  
Undecided - It is not yet known if there will be a plan to make this available