

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Effect of local injection of tranexamic acid in septoplasty surgery position on blood loss during surgery

#### Protocol summary

##### Summary

This randomized, double-blind study will do in patients who was 60 -20 years old with ASA I and for septoplasty surgery admitted to Army 501 Hospital . Patients with random allocation of sampling and using black cards (Group A) and white (group two) are divided into two groups of 30 people. In both groups after induction of identical anesthesia to reduce the amount of intraoperative bleeding, without the surgeon, anesthesiologist and patient data collector knowledge from syringes content, for Black Cards patients (syringe A) content of the syringe as lidocaine soaked in adrenaline just 1 in 100 thousand routine and in the white card patients (syringe B) content in addition to lidocaine and adrenaline syringe containing 100 mg of transamin. After the start of operation variables study by a person responsible for collecting information regarding the contents of the syringe, are recorded in the questionnaire. In this study, to determine surgeon satisfaction of at least satisfaction and the number 5 represents the number 0 and 10 equivalent full satisfaction expressed moderate satisfaction. Also on the visual analog scale for determining the amount of bleeding Scoring the practice field or position in terms of suitability to operate digit 0 is equivalent to a minimum of bleeding and digit 5 represents the average rate of bleeding and digit 10 represent excessive bleeding

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201604145536N6**  
Registration date: **2016-05-15, 1395/02/26**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-15, 1395/02/26

##### Registrant information

###### Name

Mohamadreza Rafiei

###### Name of organization / entity

Artesh University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8802 8933

###### Email address

mo\_rafiei@armyums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Army University of Medical Sciences

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of local injection of tranexamic acid in septoplasty surgery position on blood loss during surgery

##### Public title

Effect of local injection of tranexamic acid on blood loss

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Exclusion criteria: over 60 years old patients with ASAI  
Including criteria: ASA Class III, II and IV patients ,

patients with bleeding disorders, history of thromboembolism, low platelet counts and with impaired coagulation tests (PT and PTT)

#### Age

From **20 years** old to **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Army University of Medical Sciences

##### Street address

west fatemi-etemadzadeh

##### City

Tehran

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

IR.AJAUMS.REC.1394.45

## Health conditions studied

### 1

#### Description of health condition studied

Septoplasty

#### ICD-10 code

J34.2

#### ICD-10 code description

Deflection or deviation of septum (nasal)(acquired)

## Primary outcomes

### 1

#### Description

Bleeding after septoplasty

#### Timepoint

After operation

#### Method of measurement

Visual Analog Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

For black card patients (syringe A) soaked lidocaine to adrenaline will inject 1 in 100000

#### Category

Treatment - Drugs

### 2

#### Description

In white card patients (syringe B) in addition to lidocaine and adrenalin, 100 mg of trans-amine will inject

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

501 AJA Hospital

##### Full name of responsible person

Dr. Mohamadreza Rafiei

##### Street address

West fatemi street, Etemadzadeh street, Artesh University of Medical Sciences

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Army University of Medical Sciences

##### Full name of responsible person

Research director, Faculty of Medicine

##### Street address

West fatemi, Etemadzadeh st.

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

**organization/entity?**

Yes

**Title of funding source**

Army 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**

Army University of Medical Sciences

**Full name of responsible person**

Dr. Mohamadreza Rafiei

**Position**

Specialty board of anesthesia & ICU

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

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**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*