

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

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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