Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effect of intravenous tranexamic acid on intraoperative bleeding during elective rhinoplasty surgery

Protocol summary

Summary

1-(Objectives): This study aims to assess the role of intravenous Tranexamic Acid (TA) in reducing intraoperative bleeding during elective open rhinoplasty surgery. 2-(Design): In this single center double blinded study (phase 2) which is conducted in Imam Khomeini hospital affiliated to Ahvaz Jundishapour University of Medical Sciences, ninety-six patients are randomly allocated to one treatment arm with tranexamic acid and one control group. 3-(Setting and Conduct): Subjects are recruited for inclusion during their initial visit in the outpatient setting through an interview. 4-(Participants): Inclusion criteria: Normotensive patients scheduled for elective open rhinoplasty aged 16-42 years without a history of bleeding diathesis with ASA (American Society of Anesthesiologists) class of either I or II. Exclusion Criterai: patients with uncontrolled hypertension; history of hypersensitivity to tranexamic acid; brain vascular diseases; coronary artery diseases; cardiac dysrhythmia; liver/kidney or metabolic disorders; patients with ASA class of either III or IV. 5-(Interventions): All subjects will undergo open rhinoplasty under general anesthesia with the same surgical team using standard technique; Individuals in the treatment group will receive an intravenous bolus of tranexamic acid (10 milligrams per kilogram of body weight) immediately after anesthesia induction in the operation room, while patients in the control group are administered with normal saline as the placebo. 6-(Primary Outcome Variable): The primary outcome measure is the estimated volume of intraoperative bleeding (measured in mL). No secondary outcome measures are defined.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015092824241N1**

Registration date: **2015-11-07, 1394/08/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-07, 1394/08/16

Registrant information

Name

leila Mashali

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1292 1839

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2014-10-01, 1393/07/09

Expected recruitment end date

2015-10-01, 1394/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of intravenous tranexamic acid on intraoperative bleeding during elective rhinoplasty surgery

Public title
Effect of Tranexamic Acid On intraoperative Bleeding
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Normotensive patients scheduled for elective open rhinoplasty aged 16-42 years without a history of bleeding diathesis with ASA (American Society of Anesthesiologists) class of either I or II. Exclusion Criterai: patients with uncontrolled hypertension; history of hypersensitivity to tranexamic acid; brain vascular diseases; coronary artery diseases; cardiac dysrhythmia; liver/kidney or metabolic disorders; patients with ASA class of either III or IV.
Age
From **16 years** old to **42 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
A statistician not otherwise involved in the study provides the randomization sequence using an electronic random number generator (Microsoft Excel Program). Allocation letters are sealed using envelopes in which tranexamic acid or normal saline solutions are provided which look indistinguishable.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapour University of Medical Sciences
Street address
Ethics Committee, It & Research Assistance Center, University complex, Golestan Highway
City
Ahvaz
Postal code
Approval date
2015-06-06, 1394/03/16
Ethics committee reference number
IR.AJUMS.REC.1394.153

Health conditions studied

1

Description of health condition studied
Intraoperative Bleeding during Rhinoplasty
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Estimated amount of intraoperative bleeding
Timepoint
During surgery (starting from the incision till wound closure)
Method of measurement
The volume of blood suctioned during a surgery is calculated by subtracting the amount of irrigation fluid used during a surgery from the total amount of fluid gathered in suction canister at the end of surgery. The volume of blood absorbed by 4*4 inch gauzes during an operation is calculated by multiplying the number of gauzes completely soaked with blood by 10 milliliters (an estimated average of blood absorbed per gauze). These two values are then added to estimate the total intraoperative volume of blood loss.

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Intervention Group 1: Study subjects in the treatment arm will be administered with a bolus intravenous dose of tranexamic acid (10 milligram per kilogram, Caspian – Tamin Pharmaceutical Company, Rasht, Iran) which is transfused slowly after anesthesia induction. Anesthesia is attempted similarly for all patients. Briefly, propofol 2 milligram per kilogram (mg/kg) and fentanyl 1 microgram per kilogram are transfused with the aim of induction. Intravenous Atracurium (0.5 mg/kg) is infused to facilitate orotracheal intubation and anesthesia will be maintained using isoflurane inspired at a flow rate of 5 liters per minute in combination with air 30% in oxygen.

Intravenous neostigmine 0.04 mg/kg and atropine 0.01 mg/kg will be used to reverse neuromuscular blockage at the end of operation.

Category

Prevention

2

Description

Control Group: Subjects in the control group will receive normal saline as the placebo. Anesthesia is attempted similarly for all patients. Briefly, propofol 2 milligram per kg and fentanyl 1 micro-gram per kilogram are transfused with the aim of induction. Intravenous Atracurium (0.5 mg/kg) is infused to facilitate orotracheal intubation and anesthesia will be maintained using isoflurane inspired at a flow rate of 5 liters per minute in combination with air 30% in oxygen. Intravenous neostigmine 0.04 mg per kg and atropine 0.01 mg per kg will be used to reverse neuromuscular blockage at the end of operation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ear Nose and Throat Outpatient Clinic affiliated to Ahvaz University of Medical Sciences

Full name of responsible person

Ali Ghazipoor

Street address

Department of Ear Nose and Throat Surgery, Imam Khomeini Hospital, Azadegan Ave

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Nader Saki, Deputy of research development

Street address

IT & research center, University complex

City

Ahvaz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for Research of Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ali Ghazipoor

Position

Associate Professor of Ear Nose and Throat Surgery

Other areas of specialty/work

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Department of Ear Nose and Throat Surgery, Imam Khomeini Hospital, Azadegan Avenue

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ali Ghazipoor

Position

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Other areas of specialty/work

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Position
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Other areas of specialty/work

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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