

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluating the Effect of Local Tranexamic Acid on Reducing of Hemorrhage During and After Septorhinoplasty

Protocol summary

Summary

This is a randomized double-blind clinical trial (in terms of the patients, surgeon and researcher) which investigates patients who undergone open septorhinoplasty in Amiarlmoemenin hospital, Rasht. The condition to enter this study is indication of septorhinoplasty and conditions to exit this study are patients' disagreement to take part in the study, past allergic reaction to lidocaine or tranexamic acid, uncontrolled blood pressure(MAP>120, SBP>160), aspirin or any anticoagulant or anti-platelet agent intake, past history of thrombophilia or thromboembolic accidents, any abnormality in investigations which include PT, PTT, INR>1 before surgery, color vision disturbance and positive seizure history. After taking written consent from patients, 196 patients are divided into two groups (who receive placebo is P, and who receive drug is T) by an operating technician who is blinded based on a computerized program. Demographic information of the patients which consist of sex, age, height, weight, past medical history and drug history are registered. Patients undergo a general anesthesia with the same method, in T group lidocaine 2% 5ml, Aqua destillata 2.5ml, adrenaline 1/10000 0.1ml, Tranexamic acid 10% 2.5 ml, and in P group lidocaine 2% 5ml, Aqua destillata 5ml, adrenaline 1/10000 0.1ml, will be used to induce local anesthesia. Then to induce local anesthesia, the anesthesia solution will be injected as below: 2 ml into septum, 2 ml into the incision site, 1-1.5 ml into hump site, 2-2.5 ml into lateral osteotomy site. Septorhinoplasty is performed by an ENT specialist with standard method. Bleeding from operation site is evaluated by ml based on blood volume suctioned and the satisfaction of ENT specialist from operation site is a number from 1 to 3, 1: good (mild bleeding), 2: moderate (bleeding is present but does not interfere with operation process), 3: bad (severe bleeding causes operation site to be unclear to the surgeon). Finally, the volume of the serum used for washing operation site is reduced from

the total volume of the liquid in the suction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701291138N24**

Registration date: **2017-02-20, 1395/12/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the Effect of Local Tranexamic Acid on Reducing of Hemorrhage During and After Septorhinoplasty

Public title
The Effects of Local Tranexamic Acid on Reducing of Hemorrhage in Septorhinoplasty

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:The condition to enter this study is indication of septorhinoplasty; Exclusion criteria: patients' disagreement to take part in the study; past allergic reaction to lidocaine or tranexamic acid; uncontrolled blood pressure(MAP>120, SBP>160); aspirin or any anticoagulant or anti-platelet agent intake; past history of thrombophilia or thromboembolic accidents; any abnormality in investigations which include PT, PTT, INR>1 before surgery; color vision disturbance and positive seizure history;

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **196**

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
Ethics committee of Guilan University of Medical Sciences
Street address
Tehran avenue
City

Raht
Postal code
Approval date
2016-05-23, 1395/03/03
Ethics committee reference number
IR.GUMS.REC.1395.22

Health conditions studied

1

Description of health condition studied
Hemorrhage
ICD-10 code
I84
ICD-10 code description
Haemorrhoids

Primary outcomes

1

Description
The volume of bleeding during surgery
Timepoint
During surgery
Method of measurement
Blood volume suctioned by ml

2

Description
The volume of bleeding after surgery
Timepoint
The first 24 hours after surgery
Method of measurement
The number of Gauze and Volume of bleeding(Likert scale)

Secondary outcomes

1

Description
Surgeon Satisfaction
Timepoint
During surgery
Method of measurement
Likert scale

Intervention groups

1

Description
Group T: 2.5 ml Aqua destillata,5 ml Lidocain 2%, 0.1 ml Adrenalin1/100000, 2.5ml Tranexamic Acid 10%
Category
Prevention

2

Description

Group P: 5 ml Aqua destillata, 5 ml Lidocain 2%, 0.1ml Adrenalin 1/100000

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan University of Medical Sciences

Full name of responsible person

Dr Ali Faghih Habibi

Street address

Amiralamomenin Hospital, 17 shahrivar St

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Susan Komaee

Street address

Vice-chancellor for Research Building, Opposite of Sepah Bank, Shahid Beheshti Blvd(west)

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan University of Medical Sciences, Vice Chancellor for 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

Guilan University of Medical Sciences

Full name of responsible person

Dr Ali Faghih Habibi

Position

Assistant Professor

Other areas of specialty/work

Street address

Amiralamomenin Hospital, 17 shahrivar St

City

Rasht

Postal code

Phone

+98 13 3322 5242

Fax

Email

dr.faghih.habibi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Ali Faghih Habibi

Position

Assistant Professor

Other areas of specialty/work

Street address

Amiralamomenin Hospital, 17 shahrivar St

City

Rasht

Postal code

Phone

+98 13 3322 5242

Fax

Email

dr.faghih.habibi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Fatemeh Nezamdoust

Position

Msc

Other areas of specialty/work

Street address

Amiralamomenin Hospital, 17 shahrivar St

City

Rasht

Postal code

Phone

+98 13 3322 5242

Fax

Email

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