Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the effect of tranexamic acid and intravenous desmopressin on reducing bleeding during septorhinoplasty.

Protocol summary

Study aim

Comparison of the effect of tranexamic acid and intravenous desmopressin on reducing bleeding during septorhinoplasty.

Design

This study is a randomized, double-blind, phase 3 clinical trial with a sample size of 175 patients randomly assigned to three groups. The first group receives tranexamic acid. The second group received desmopressin. And the third group is given placebo

Settings and conduct

n this study, 177 patients undergoing septorhinoplasty will be divided into three groups including intravenous tranexamic acid, intravenous desmopressin and placebo. All patients will receive the same premedication and all patients will receive propofol during surgery. and remifentanil is given during the operation depend on the blood pressure and heart rate and if the blood pressure is not controlled, propofol will increase and then Depending on the heart rate and blood pressure, TNG and labetalol will be used. The amount of bleeding is determined by the volume of the suction and the amount of blood in the gases. Surgeons' satisfaction from the operating field is measured by a questionnaire. The PT, PTT, INR and platelet counts were compared before and after the surgery. This study was performed at Rasool Akram Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Perform Septorhinoplasty No coagulation disorders 18 Years until 50 Years ASA-1

Intervention groups

In the first intervention group, Tranexamic acid was injected half an hour before surgery at a dose of 5 mg / kg. And in the second intervention group Desmopressin injected at 4 µg / ml half an hour before surgery And in the control group the same amount of placebo is given with similar characteristics.

Main outcome variables

Age Gender Suction volume Number of gases PT PTT INR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200124046241N1**
Registration date: **2020-03-01, 1398/12/11**
Registration timing: **retrospective**

Last update: **2020-03-01, 1398/12/11**
Update count: **0**

Registration date

2020-03-01, 1398/12/11

Registrant information

Name

Taimaz Amiraslani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2278 5427

Email address

golezard1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2019-03-21, 1398/01/01

Actual recruitment end date

2019-08-23, 1398/06/01

Trial completion date

2019-08-23, 1398/06/01

Scientific title

Comparison of the effect of tranexamic acid and intravenous desmopressin on reducing bleeding during septorhinoplasty.

Public title

Comparison of the effect of tranexamic acid and intravenous desmopressin on reducing bleeding during septorhinoplasty.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Perform septorhinoplasty No coagulation disorders 18 Years until 50 Years ASA-1

Exclusion criteria:

Contraindications for the administration of Tranexamic acid and Desmopressin Dissatisfaction with research Drug addiction Being a smoker

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator

Sample size

Target sample size: **175**

Actual sample size reached: **175**

Randomization (investigator's opinion)

Randomized

Randomization description

This study was designed as a clinical trial in which the number of patients was determined according to the sample size formula and the patients were randomly selected using a simple randomization method that provided a data code to each patient using a random number table. By random selection of the code, patients were assigned to three treatment groups without observing the patients' codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher is unaware of the process of prescribing medications and control groups, as well as those who provide care and treatment to the patients participating in the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

No. 16, Karimi Ave., Yarmohammadi Ave., Daroos Ave., Pasdaran Town

City

Tehran

Province

Tehran

Postal code

1944644651

Approval date

2018-04-04, 1397/01/15

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9511174002

Health conditions studied

1

Description of health condition studied

Septorhinoplasty

ICD-10 code

B46.1

ICD-10 code description

Rhinocerebral mucormycosis

Primary outcomes

1

Description

Bleeding

Timepoint

During surgery

Method of measurement

The amount of bleeding is determined by the volume of the suction and the number of blood gases.

Secondary outcomes

1

Description

Blood pressure

Timepoint

During surgery

Method of measurement

With barometer

2

Description

Heart rate

Timepoint

During surgery

Method of measurement

Pulse Oximeter

Intervention groups

1

Description
Intervention group: Intravenous tranexamic acid, produced by Caspian Drug Co., 500 mg / 5 ml, half an hour before surgery, 5 mg / kg, intravenously.
Category
Treatment - Drugs

2

Description
Intervention group: Desmopressin is an injection produced by the Razavi Pharmaceutical Services Institute, which is administered intravenously at a dose of 4 µg / ml once a half hour before surgery.
Category
Treatment - Drugs

3

Description
Control group: Placebo is similar to both transaminic acid and desmopressin from distilled water and used intravenously half an hour before surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul akram hospital
Full name of responsible person
Taimaz Amiraslani
Street address
No. 16, Karimi Ave., Yarmohammadi Ave., Daroos Ave., Pasdaran Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Taimaz Amiraslani
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
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
Iran University of Medical Sciences
Full name of responsible person
Taimaz Amiraslani
Position
Doctor
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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No. 16, Karimi Ave., Yarmohammadi Ave., Daroos Ave., Pasdaran Town
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Person responsible for scientific

inquiries

Contact

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Taimaz Amiraslani

Position
Doctor

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Person responsible for updating data

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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