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
In 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

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
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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
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Province
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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
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inquiries

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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