Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect Of Desmopressin Intraoperatively On Hemorrhage During The Rhinoplasty

Protocol summary

Study aim
To Evaluate the role of Desmopressin in the prevention of intraoperative hemorrhage in Rhinoplasty.

Design
Randomized double-blind placebo-control study. Randomization is done by block randomization. The total sample size is 70 patients.

Settings and conduct
The setting of the study: the emergency department and clinic of Amir Alam Hospital by an attending physician. After patient selection, they will be referred to our research center for randomization and documentation. Paraclinical tests such as Complete Blood Count, PT, PTT, and INR will be performed. Patients and physicians are blinded during the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Volunteers with no age limit who undergo the Rhinoplasty Exclusion criteria: Cardiovascular disease Bleeding disorders High blood pressure Allergy to Desmopressin History of cerebrovascular attack Seizure

Intervention groups
70 patients will be divided into two groups-35 patients in the intervention group and 35 patients in the placebo group- (N1 = N2 = 35). In the intervention group, thirty minutes before the surgery, 500 ml of normal saline containing 0.1µgr / kg of Desmopressin will be injected. In the control group, thirty minutes before the surgery, 500 ml of normal saline will be injected.

Main outcome variables
-Bleeding during the Rhinoplasty will be measured by the sucker bottle which is calibrated and measures bleeding loss -Bleeding will be measured also by the surgeon based on the FROMME-BOEZAART Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170120032069N7**
Registration date: **2020-06-20, 1399/03/31**
Registration timing: **prospective**

Last update: **2020-06-20, 1399/03/31**
Update count: **0**

Registration date
2020-06-20, 1399/03/31

Registrant information

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Ardavan Tajdini

Name of organization / entity
Tehran University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect Of Desmopressin Intraoperatively On Hemorrhage During The Rhinoplasty

Public title
Effect of Desmopressin on Bleeding During The Nose Job
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Volunteers with no age limit who undergo the Rhinoplasty
Exclusion criteria:
Cardiovascular disease Bleeding disorders High blood pressure Allergy to Desmopressin History of cerebrovascular attack Seizure
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The blocking method will be used to select patients in one of the two intervention and control arms so that they are selected using the random numbers table of the 4 blocks and then the items will be selected and introduced with time review.Foursquare blocks of intervention group(A) and control(B) are defined on cards 1-6 (AABB,ABAB,ABBA,BBAA,BABA,BAAB), the cards are placed inside the envelope. Then the cards are selected randomly and then the random string is created from the sequence of selected cards. Patients in the intervention and control group are included in the study according to this sequence
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, principal investigators, and other investigators, physicians, nurses, anesthesiologists, pharmacists, data collectors, outcome assessors are blinded during the study about kind of drug (steroid+plasebo or steroid+omega-3) that patients will take.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-Chancellor in Research Affairs- Tehran University of Medical
Street address
University of Medical Sciences, Ghods St, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
11457-65111
Approval date
2019-03-02, 1397/12/11
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.897

Health conditions studied

1

Description of health condition studied
Rhinoplasty and haemorrhage during the surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
bleeding during rhinoplasty surgery
Timepoint
Measuring the amount of bleeding at the end of surgery
Method of measurement
The sucker bottle which is calibrated measures bleeding loss

2

Description
view of surgeon on operating field
Timepoint
Measuring surgeon satisfaction at the end of surger
Method of measurement
based on the FROMME-BOEZAART Scale

3

Description
The time of surgery
Timepoint
Measuring the time of surgery at the end of surgery
Method of measurement
Duration of surgery from the begining to the end of the surgery

Secondary outcomes

1

Description
Bleeding will be measured by the surgeon based on the FROMME-BOEZAART Scale
Timepoint
During the surgery
Method of measurement
Based on this scale, there are five grades in which the surgeon during the surgery scores the bleeding. Grade 0: No bleeding (cadaveric conditions); grade 1: Slight bleeding, no suctioning required; grade 2: Slight bleeding, occasional suctioning required; grade 3: Slight bleeding, frequent suctioning required; bleeding threatens surgical field a few seconds after suction is removed; grade 4:Moderate bleeding, frequent suctioning required, and bleeding threatens surgical field directly after suction is removed; grade 5:Severe bleeding, constant suctioning required; bleeding appears faster than can be removed by suction; surgical field severely threatened and surgery usually not possible

Intervention groups

1

Description
Intervention group: Thirty minutes before the surgery, 500 ml of normal saline containing 0.1µgr / kg of Desmopressin is injected.
Category
Treatment - Drugs

2

Description
Control group: Thirty minutes before the surgery, 500 ml of normal saline is injected.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralam Hospital,Tehran University of Medical Siences
Full name of responsible person
Dr. Ardovan Tajdini
Street address
Amiralam Hospital,North Saadi St,District 12
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Amir Hossein Ghabasiah
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
We will share all collected deidentified individual-patient data (IPD) underlying the results presented in the article (including tables, figures, and appendices or supplementary material),study protocol, statistical analysis Plan, informed consent form, clinical study report, analytic code.
When the data will become available and for how long
Beginning 3 months and ending 5 years following article publication
To whom data/document is available
Researchers who provide a methodologically sound proposal
Under which criteria data/document could be used
To access the data, they must specify the type of data and specify the type of data to use.
From where data/document is obtainable
Applicants should make a formal request by email,then they will get data by email. Email address: AH.ghabasiah@gmail.com
What processes are involved for a request to access data/document
After submitting the request by email, their request will be reviewed by the research team and Up to 6 months after the request is submitted, their request will be sent to their email address.
Comments