Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical Trial of Evaluation of the effects of intranasal desmopressin on intraoperative blood loss and quality of the surgical field during open rhinoplasty:

Protocol summary

Study aim
Evaluation of the effects of topical intranasal desmopressin on intraoperative bleeding and surgical field quality during open rhinoplasty

Design
Clinical trial with control group with parallel groups, double-blind, randomized, phase 3 on 120 patients,PASS11 software was used for randomization.

Settings and conduct
patients 18-40 Y/O referred to Amir Al-Momenin Hospital for rhinoplasty in the period 1400-1399, are randomly divided into three groups by a researcher and two blind-sided patients are given one placebo group and two groups of drugs.Randomization is performed by a researcher who is not involved in the clinical stages of the project, and surgery is performed by a surgeon who is unaware of the study group.

Participants/Inclusion and exclusion criteria
People 18-40 Y/O who refer to AmirAl-Momenin Hospital,a candidate for rhinoplasty,are inclusion criteria. Exclusion criteria: 1. People with abnormal coagulation tests 2. People with a history of cardiovascular disease 3. Patients with vascular disease 4. People taking anticoagulants 5. Patients with brain diseases, hypertension and diabetes 6. Pregnancy 7. History of seizures 8.Consumers of complementary and herbal medicines and vitamin E. 9. Consumers of corticosteroids in the last two weeks 10. Consumers of diuretics 11. Vulnerable groups 12. History of previous rhinoplasty

Intervention groups
Patients randomly divided into three groups. Each patient gets 2 spray puffs in each nostril. The first group received topical desmopressin 1 puff per nostril and normal saline spray received one puff per nostril, and the second group received 2 puffs topical desmopressin per nostril and the third group receives placebo 2 puffs per nostril. Patients do not know what group they belong to

Main outcome variables
Quality of the surgical field, blood loss, complications during operation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200708048051N3**
Registration date: **2021-02-20, 1399/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-20, 1399/12/02**
Update count: **0**

Registration date
2021-02-20, 1399/12/02

Registrant information

Name
Malihe Akbarpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3261 9301

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akbarpour@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01

Expected recruitment end date
2021-09-21, 1400/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical Trial of Evaluation of the effects of intranasal desmopressin on intraoperative blood loss and quality of the surgical field during open rhinoplasty:

Public title
Evaluation of the effects of intranasal desmopressin on intraoperative blood loss and quality of the surgical field during open rhinoplasty
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients 18 to 40 years old who are candidates for rhinoplasty
Exclusion criteria:
People with abnormal coagulation tests People with a history of cardiovascular disease Patients with coagulation diseases People taking anticoagulants Patients with brain diseases, hypertension and diabetes Pregnant women History of seizures Consumption of herbal supplements and vitamin E. Corticosteroid users in the last two weeks Consumers of diuretics Vulnerable groups History of previous rhinoplasty
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
After receiving explanations about the project, the patients were randomly divided into three groups of intervention with high-dose desmopressin, intervention with low-dose desmopressin and the control group by block randomization. Blocking is used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. First, the software prepares a list of 4 blocks in which an equal number of people are randomly divided into three groups A, B and C. This list is placed in a separate envelope and then the envelope is closed and given to a third person. If the patient visits and is eligible, one of the envelopes will be given to the patient according to the number. After filling out the forms, the envelope is opened and based on the desired number, the patient is treated and receives the relevant intervention. Patients and researchers will not be aware of the type of intervention received.
Blinding (investigator's opinion)
Double blinded
Blinding description
Individual under study, physicians caring for patients, and those who assess the outcomes, researchers of the project are kept blind to the assignment to different groups. After selecting the patients, the medications are given to the patients in similar and unnamed envelopes by a third person. The list of patients in each group will not be disclosed until the end of the data analysis.
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
Vice chancellor for Research building, opposite of Sepah Bank, Shahid Beheshti Blv.
City
Rasht
Province
Guilan
Postal code
4139637459
Approval date
2021-01-13, 1399/10/24
Ethics committee reference number
IR.GUMS.REC.1399.505

Health conditions studied

1

Description of health condition studied
Rhinoplasty surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of the surgical field during surgery

Timepoint
During the operation
Method of measurement
The quality of the surgical field is determined by the surgeon during the operation based on the BOEZAART criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Topical desmopressin spray inside the nose, one puff in each nostril (equivalent to 20 micrograms) one hour before surgery
Category
Treatment - Drugs

2

Description
Intervention group 2: Topical desmopressin spray 2 puffs in each nostril (equivalent to 40 micrograms) one hour before surgery
Category
Treatment - Drugs

3

Description
Control group: Topical desmopressin spray 2 puffs in each nostril (equivalent to 40 micrograms) one hour before surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al-Momenin Hospital
Full name of responsible person
Maliheh Akbarpour
Street address
Amir Almomenin Hospital, 17 shahrivar streetht
City
Rasht
Province
Guilan
Postal code
4139638459
Phone
+98 13 3323 8308
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akbarpour@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammad Reza Naghipour
Street address
Vice-chancellor for research building, opposite of Sepah bank, Shahid Siadati Ave, Namjoo Blv
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4139637459
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naghi@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Maliheh Akbarpour
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
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Person responsible for updating data

Contact
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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
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
Title and more details about the data/document
After the end of the study period
When the data will become available and for how long
After the end of the study period
To whom data/document is available
At the end of the study period, the results will be available to the public in the form of an article
Under which criteria data/document could be used
In case of publication in the form of an article
From where data/document is obtainable
ENT Center of Guilan University of Medical Sciences
What processes are involved for a request to access data/document
In-person referral or electronic request to the ENT Center of Guilan University of Medical Sciences
Comments