

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 13 3261 9301

Email address

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipour

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Vice-chancellor for research building, opposite of Sepah bank, Shahid Siadati Ave, Namjoo Blv

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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

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