

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 functional endoscopic sinus surgery

Protocol summary

Study aim

Evaluation of the effects of topical intranasal desmopressin on intraoperative bleeding and surgical field quality during endoscopic sinus surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 120 patients. PASS 11 software was used for randomization.

Settings and conduct

Patients aged 18 to 55 years with chronic rhinosinusitis referred to Amir Al-Momenin Hospital in Rasht in the period of 1399-1400 are randomly divided into three groups by a blind researcher. A group of placebo and two groups of drugs are given. 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 not aware of the study group.

Participants/Inclusion and exclusion criteria

All patients aged 18 to 55 years with a diagnosis of chronic rhinosinusitis who have not responded to maximal drug treatment and are candidates for functional endoscopic sinus surgery. Exclusion criteria: 1- People with a history of cardiovascular diseases 2- Patients with coagulation diseases 3 - People who take anticoagulants 4- Patients with brain diseases and high blood pressure 5- Patients with nasal and sinus tumors 6- Pregnant women 7- Consumption of herbal medicines 8- History of previous sinus surgery 9- Corticosteroid drugs users 10- Consumers of diuretic drugs

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 surgical field, blood loss and complications during the operation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200708048051N2**

Registration date: **2021-02-12, 1399/11/24**

Registration timing: **prospective**

Last update: **2021-02-12, 1399/11/24**

Update count: **0**

Registration date

2021-02-12, 1399/11/24

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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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-08-23, 1400/06/01

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 functional endoscopic sinus surgery

Public title

Evaluation of the effects of intranasal desmopressin on intraoperative blood loss and quality of the surgical field during functional endoscopic sinus surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

all patients with chronic rhino-sinusitis with or without nasal polyps candidate for functional endoscopic sinus surgery

Exclusion criteria:

patients with abnormal coagulation tests patients with history of cardiovascular disease patients with coagulopathy anticoagulant drug users patients with cerebrovascular disease patients with sinonasal tumors pregnant women herbal or vitamin E drug users sinus revision surgery corticosteroid drug users diuretic drug users patients with high systemic blood pressure

AgeFrom **18 years** old to **55 years** old**Gender**

Both

Phase

3

Groups that have been masked

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

Sample sizeTarget 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

2021-01-19, 1399/10/30

Ethics committee reference number

IR.GUMS.REC.1399.504

Health conditions studied**1****Description of health condition studied**

chronic rhinosinusitis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

Quality of the surgical field during surgery.

Timepoint

during surgery

Method of measurement

The quality of the surgical field is determined by the surgeon during the operation according to the BOEZAART criteria.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Topical desmopressin spray, 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: Placebo containing normal intranasal topical saline spray with the same shape as topical intranasal desmopressin spray, two puffs in each nostril 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

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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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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

At the end of the study period, all potential data can be shared after unidentifying individuals.

When the data will become available and for how long

6 months after printing the results.

To whom data/document is available

At the end of the study period, the results, data and documentation will be made available to all researchers.

Under which criteria data/document could be used

Data and documentation will be provided to researchers to help advance and complete similar research projects.

From where data/document is obtainable

ENT Research Center of Guilan University of Medical Science

What processes are involved for a request to access data/document

In-person referral or electronic request to the ENT Research Center of Guilan University of Medical Science

Comments