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 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 refered 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
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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
Age
From **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 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
2021-01-19, 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
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Sponsors / Funding sources

1

Sponsor
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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
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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 Univercity 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 Univercity of Medical Science
Comments