

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The Effect of nasal spray of desmopressin administration on intraoperative blood loss and quality of the surgical field during functional endoscopic sinus surgery in patients with chronic rhino sinusitis

Protocol summary

Study aim

Comparison of the effects of nasal spray of desmopressin versus placebo on blood loss and the quality of the surgical field in endoscopic sinus surgery

Design

Randomized double-blind clinical trial

Settings and conduct

Patients were randomly allocated to two groups of desmopressin and placebo. The patients and analyst were blinded to the assignments, but the investigator and carers of the patients were informed. The setting was Rasoul Akram university hospital.

Participants/Inclusion and exclusion criteria

All patients must be 18–65 years old, and it is their first-time candidates for two-side FESS ;exclusion criteria are as follows: patients with a history of bleeding disorders or taking medications that may affect surgical hemostasis; secondary surgery; poorly controlled hypertension or cerebrovascular disease; a history of significant coronary artery disease or arrhythmias; a compromised renal or hepatic function; and pregnancy.

Intervention groups

Desmopressin

Main outcome variables

Intraoperative blood loss; quality of the surgical field during functional endoscopic sinus surgery; bleeding after the surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101026005026N9**

Registration date: **2018-05-08, 1397/02/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-08, 1397/02/18**

Update count: **0**

Registration date

2018-05-08, 1397/02/18

Registrant information

Name

Masood Mohseni

Name of organization / entity

Rasul Akram hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2326

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of nasal spray of desmopressin administration on intraoperative blood loss and quality of the surgical field during functional endoscopic sinus surgery in patients with chronic rhino sinusitis

Public title

The Effect of desmopressin administration on intraoperative blood loss of sinus surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients must be 18–65 years old, who it is their first-time candidates for two-side FESS

Exclusion criteria:

Patients with a history of bleeding disorders or taking medications that may affect surgical homeostasis; Poorly controlled hypertension or cerebrovascular disease; A history of significant coronary artery disease or arrhythmia Secondary surgery Pregnancy A compromised renal or hepatic function; and

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly allocated to the Desmopressin or Placebo groups. Simple Randomization was performed, using a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, outcome assessor and data analyser were blinded to the assignments.

Placebo

Used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran university of medical Sciences

Street address

Hemmat Highway, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2017-12-11, 1396/09/20

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9411174018

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

Bleeding during endoscopic surgery of sinuses (FESS)

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes**1****Description**

Intraoperative blood loss

Timepoint

Every 15 minutes from the beginning of anesthesia until maximum 90 minutes

Method of measurement

Final intraoperative blood loss was confirmed at the end of each procedure by accounting for loss of blood and irrigation fluid into the suction canister, and nasopharyngeal packing (measured weight of packing on the electronic scale)

2**Description**

Quality of the surgical field during functional endoscopic sinus surgery

Timepoint

End of surgery

Method of measurement

A scoring scale adapted from Boezaart and van der merew

Secondary outcomes**1****Description**

Bleeding after the surgery

Timepoint

Until 4 days after surgery

Method of measurement

Questionnaire

Intervention groups

1

Description

One puff Desmopressin nasal spray (10 µg) in either nostril before anesthesia

Category

Treatment - Drugs

2

Description

One puff nasal spray of normal saline in either nostril before anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Masood Mohseni

Street address

Rasoul Akram hospital, Niayesh Ave, Sattarkhan St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Alijavad Mosavi

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Masood Mohseni

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Arman Ghandi

Position

Resident of Anesthesiology

Latest degree

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data regarding primary and secondary outcomes will be available

When the data will become available and for how long

Immediately after publication

To whom data/document is available

Only faculty members and academic institutions

Under which criteria data/document could be used

The result of further analysis may not be presented to public without permission

From where data/document is obtainable

masood.mohseni@gmail.com

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

A reasonable request from an academic source will be responded within 10 working days

Comments