

# 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

mohseni@med.mui.ac.ir

##### 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

#### City

Tehran

#### Province

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#### Postal code

1445613131

#### Phone

+98 21 6435 2326

#### Email

Masood.Mohseni@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Alijavad Mosavi

#### Street address

Rasoul Akram hospital, Niayesh Ave, Sattarkhan St

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#### Email

mohseni@med.mui.ac.ir

#### 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

#### Street address

Rasool Akram hospital, Niayesh Ave, Sattarkhan St

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#### Postal code

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#### Email

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## Person responsible for scientific 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 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**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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Dr.arman.ghandi@gmail.com

**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**