

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of local desmopressin administration on intraoperative blood loss and quality of the surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis

Protocol summary

Study aim

Finding cost effective method to decrease bleeding and improve the visual field of the surgery in the patients who candidate for functional endoscopic sinus surgery

Design

Triple blinded, clinical trial with 88 patients

Settings and conduct

Patients undergoing endoscopic sinus surgery who have been referred to otolaryngology clinic of Hamadan Besat hospital, since the adoption of the plan for one year, will be included in the study if they are eligible for entry and consents. Blind mode: Due to the type of intervention and coding, patients, researchers and analyst, do not know the contents of the used spray.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients suffering from chronic rhinosinusitis who candidates for endoscopic sinus surgery Exclusion criteria: Suffering from sinusal tumors

Intervention groups

All patients used a nasal spray with an unspecified substance, thirty minutes before the start of the surgery, in each side of the nose; the contents of the nasal sprays included Desmopressin in the case group (10 micrograms in each puff, 20 micrograms in total) and normal Saline in control group.

Main outcome variables

Amount of blood volume; visual field of surgery; blood pressure changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130713013976N5**
Registration date: **2018-04-24, 1397/02/04**

Registration timing: **retrospective**

Last update: **2018-04-24, 1397/02/04**

Update count: **0**

Registration date

2018-04-24, 1397/02/04

Registrant information

Name

Javaneh Jahanshahi

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hamadan university of medical science, researching center

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-08-01, 1396/05/10

Actual recruitment end date

2018-03-19, 1396/12/28

Trial completion date

empty

Scientific title

Effect of local desmopressin administration on intraoperative blood loss and quality of the surgical field

during functional endoscopic sinus surgery in patients with chronic rhinosinusitis

Public title

Effect of local desmopressin administration on intraoperative blood loss and quality of surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from chronic rhinosinusitis with or without polyposis Between 18 to 60 years old Normal coagulative tests and platelet count

Exclusion criteria:

Suffering from coagulative disorders like Hemophilia
Suffering from sinunasal tumors
History of thromboembolic accident
Suffering from acute or chronic renal failure
Receiving Heparin in 48 hour before surgery
Receiving Aspirin in 3 days before surgery
Allergy to Desmopressin
Liver scirrrosis
Systemic diseases like hypertension, diabet mellitus, heart failure
Pregnancy
Cardiac stent

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **88**

Actual sample size reached: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Six-block randomization is used for this purpose. Six piece of paper prepared while in 3 of them letter A and in 3 others letter B was written. After mixing the papers all of them were put in the drawer desk. For any volunteer patient one of the papers will be removed randomly and by the letters they were divide in intervention or control groups. After removal of all the papers , they were charged again. This process is continued up to achieve to samples volume.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Before starting the research and after accepting consent ,is explained to patients that they would entered in each groups of receiving topical desmopressin nasal spray(intervention) or normal saline(control group) .Because of the bottles`s same look and their filling and coding by pharmacist who participate in the research,

neither researcher nor the patients have idea about contents of the bottles and their codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Science

Street address

Ethics Committee of Hamadan University of Medical Science, Khaje Rashid Blv., Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

1234567890

Approval date

2017-04-08, 1396/01/19

Ethics committee reference number

IR.UMSHA.REC.1396.11

Health conditions studied

1

Description of health condition studied

Chronic rhinosinusitis

ICD-10 code

J32.4

ICD-10 code description

Chronic pansinusitis

Primary outcomes

1

Description

visual field of surgery

Timepoint

15,30,60,90 minutes after starting surgery

Method of measurement

Boezaart Grading

2

Description

bleeding volume

Timepoint

15,30,60,90 minutes after starting surgery

Method of measurement

blood volume in suction s bottle

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

mean arterial pressure

Timepoint

before and in points of 15,30,60 and 90 min after surgery

Method of measurement

blood pressure monitoring

2**Description**

surgery duration

Timepoint

time of starting upto end of the surgery

Method of measurement

recording duration of surgery

3**Description**

serum sodiome level

Timepoint

before and after the surgery

Method of measurement

serum sodiome level test

Intervention groups**1****Description**

Intervention group: Single puff of Desmopressin nasal spray, 30 minutes before starting the surgery in each side of nasal cavity (10 micro gram in each side). This drug complete name is Desmopressin Acetate and this study has used a product of SINA-Darou factory with concentration of 100 mcg in 1 ml (each puff contains 10 mcg as noted).

Category

Treatment - Drugs

2**Description**

Control group: Single puff of Saline 0.65% nasal spray , 30 minutes before starting the surgery in each side of nasal cavity.This study has used a product of SINA-Darou factory with concentration of 65 gr in 100 cc.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

ENT department of BESAT hospital

Full name of responsible person

Dr Javaneh Jahanshahi , Dr Elham Tayebi

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Besat hospital ENT department,Shahid Beheshti Blvd,Hamadan

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

Hamedan University of Medical Sciences

Full name of responsible person

Solgi Ghasem

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Elham Tayebi

Position

ENT resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

BESAT Hospital, Shahid Beheshti Blvd, Hamadan

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Javaneh Jahanshahi

Position

faculty member

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Elham Tayebi

Position

ENT resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of personal information and data could be shared

When the data will become available and for how long

Access starts from 6 months after results publishing

To whom data/document is available

Researchers

Under which criteria data/document could be used

Just for more researches in this field

From where data/document is obtainable

Elham Tayebi , num:09113280530, email:

e_tayyebi@yahoo.com

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

Written request and letter of introduction from the subsidiary

Comments