Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 ofHamadan 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 sinunasal 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

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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 scirrhosis 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 sodiume level
Timepoint
before and after the surgery
Method of measurement
serum sodiume 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
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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

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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