Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 2026

desmopressin effects on bleeding after functional endoscopic sinus surgery on patients with chronic rhinosinusitis with and without polyposis

Protocol summary

Study aim

Determination of the effect of desmopressin on the reduction of bleeding during surgery in FESS surgeries

Design

The blocking method will be used to select patients in one of the two intervention and control arms so that they are selected using the random numbers table of the 4 blocks and then the items will be selected and introduced with time review. It should be noted that in this study, the patients, the team of surgeons, the anesthetic team and the operating room team did not know the control or intervention of the patients.

Settings and conduct

In the operating room of Amiralam Hospital, 100 ml of normal saline was injected to both groups half an hour before surgery. In the control group, it contained only normal saline and in the intervention group containing 0.1 µgr / kg desmopressin. In this study Patients, the team of surgeons, the anesthetic team and the operating room team are unaware of the control or intervention of the patients, and the intervention group and the placebo group are both surgically treated by a professor

Participants/Inclusion and exclusion criteria

Patients with chronic Rhinosinusitis in the age group of 15-60 years without heart disease and underlying coagulation disorders, without high blood pressure

Intervention groups

In both groups, 100 ml of normal serum saline was injected half an hour before surgery. In the control group, this serum only contained normal saline and in the intervention group containing 0.1 µgr / kg desmopressin. After surgery, if the surgery field is not satisfied by the surgeon, the 100th second serum is prescribed in both groups, and after half an hour if bleeding is repeated, 100 cc is also prescribed.

Main outcome variables

Reduction of bleeding during surgery, surgeon satisfaction from the field of operation and shortening the duration of the FESS surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170120032069N5**
Registration date: **2019-11-10, 1398/08/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-10, 1398/08/19**
Update count: **0**

Registration date

2019-11-10, 1398/08/19

Registrant information

Name
Ardavan Tajdini
Name of organization / entity
Tehran University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 21 6670 3037
Email address
a-tajdini@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
desmopressin effects on bleeding after functional endoscopic sinus surgery on patients with chronic rhinosinusitis with and without polyposis

Public title
Desmopressin effects on bleeding after functional endoscopic sinus surgery on patients with chronic rhinosinusitis with and without polyposis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic rhinosinusitis in the age group of 15-60 years old No heart disease without Background coagulation disorders Without high blood pressure No history of previous FESS surgery
Exclusion criteria:
If patients are not satisfied with entering the project
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **19**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients eligible for inclusion in the study are interviewed first and explained to the project, and, if satisfied, to participate in the study, the patients will receive written consent to be included in the plan and informed of them. They will be randomly assigned to either group. The blocking method will be used to select patients in one of the two intervention and control arms so that they are selected using the random numbers table of the 4 blocks and then the items will be selected and introduced with time review. It should be noted that in this study, the patients, the team of surgeons, the anesthetic team and the operating room team did not know the control or intervention of the patients, and the intervention group and the placebo group were both surgically operated by a professor, and for both groups 100 cc My head is ready to be used, which the surgical team and the data analyst do not know about its nature.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the patients, the team of surgeons, the anesthetic team and the operating room team were unaware of the control or intervention of the patients, and the intervention group and the placebo group were both surgically treated by a professor.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-Chancellor in Research Affairs- Tehran University of Medical
Street address
Amiralam hospitla, north sadi av. Enqelab av.
City
تهران
Province
Tehran
Postal code
1145765111
Approval date
2019-06-22, 1398/04/01
Ethics committee reference number
IR.TUMS.VCR.REC. 1398.311

Health conditions studied

1

Description of health condition studied
chronic rhinosinositis with and without polyposis
ICD-10 code
chronic Rh
ICD-10 code description
chronic Rhinosinositis, polyposis, Desmopressin, FESS

Primary outcomes

1

Description
Reduce bleeding during FESS surgery - better view of surgeon on operating field -- Reduce the time of surgery
Timepoint
Measuring the amount of bleeding at the end of surgery .... Measuring surgeon satisfaction at the end of surgery .... Measuring the time of surgery at the end of surgery
Method of measurement
Calibrated container to measure the amount of bleeding. A numerical questionnaire is used to measure the surgeon's satisfaction .measure the time of operation by clock.

Secondary outcomes

1

Description
Reduce the need for postoperative blood transfusions ....
Reduce the need for intraoperative anesthesia
Timepoint
Both outcomes are measured at the end of surgery.
Method of measurement
The rate of hemoglobin loss at the end of surgery and the amount of anesthetic drugs used during surgery

Intervention groups

1

Description
Intervention group: Intervention group: 100mg normal saline containing 0.1µgr / kg desmopressin will be injected 1 min before surgery in case group. If the surgeon is dissatisfied from the operation field, a second dose of the drug is injected 30 minutes after surgery.
Category
Treatment - Drugs

2

Description
Control group: In this group, 100 ml of normal saline is injected 30 minutes before surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir-alam hospital
Full name of responsible person
Jawad Hosseini
Street address
Amir-alam hospital, north Sadee str., Enqelab st.
City
Tehran
Province
Tehran
Postal code
1145765111
Phone
+98 21 6634 3352
Email
jawadhosseini.md@gmail.com

2

Recruitment center
Name of recruitment center
Amir alam hospital
Full name of responsible person
Jawad Hosseini
Street address
Amir-alam hospital, north Sadee str., Enqelab st.
City
Tehran
Province
Tehran
Postal code
1145765111
Phone
+98 21 6634 3352
Email
jawadhosseini.md@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
Amir-alam hospital, north Sadi Ave., Enqelab Ave.
City
Tehran
Province
Tehran
Postal code
1145765111
Phone
+98 21 6634 3352
Email
a-tajdini@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Jawad Hosseini
Position

residence
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Darvaze Dolat, Saadi st, Engelab st
City
Tehran
Province
Tehran
Postal code
1145765111
Phone
+98 21 6670 6106
Fax
Email
jawadhosseini.md@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Jawad Hosseini
Position
residence
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
Street address
north Sadi Ave., Enqelab Ave.
City
Tehran
Province
Tehran
Postal code
1145765111
Phone
+98 21 6670 3037
Fax
+98 21 6670 3037
Email
jawadhosseini.md@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Jawad Hosseini
Position
residence
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
Street address
North Sadi Ave., Enqelab Ave.
City
Tehran
Province
Tehran
Postal code
1145765111
Phone
+98 21 6670 3037
Fax
+98 21 6670 3037
Email
jawadhosseini.md@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Demographic information and information of samter's Triad and Land McKay Score and the results of some tests are available.
When the data will become available and for how long
Access is available 2 years after the final results are published
To whom data/document is available
The results are accessible to researchers working in academic institutions and universities.
Under which criteria data/document could be used
To access the data, they must specify the type of data and specify the type of data to use.
From where data/document is obtainable
To receive the type of information, they can email the following email jawadhosseini.md@gmail.com
What processes are involved for a request to access data/document
After submitting the request by email, their request will be reviewed by the research team and Up to 6 months after the request is submitted, their request will be sent to their email address.
Comments