Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of Intravenous Desmopressin, Tranexamic Acid, and their combination on intra-operative bleeding during functional endoscopic sinus surgery of adults

Protocol summary

Study aim

Assessing the effect of Intravenous Desmopressin, Tranexamic Acid, and their combination on intra-operative bleeding during functional endoscopic sinus surgery in adults

Design

prospective randomized double-blind clinical trial

Settings and conduct

The study uses double-blind randomization. Participants are assigned to groups using sealed, opaque envelopes, ensuring neither participants nor investigators know the group assignments. This approach aims to reduce bias and improve study reliability.

Participants/Inclusion and exclusion criteria

The study includes adults aged 18-65 undergoing their first bilateral FESS for chronic rhinosinusitis with polyps. Eligible patients must have normal preoperative tests (platelet count, PT, PTT, INR, hemoglobin, BUN, creatinine, sodium, potassium) and be classified as ASA I or II. Excluded are those with Wegener's disease, sarcoidosis, sinonasal cancer, bleeding disorders, allergies to TXA/DDAVP, thromboembolic diseases, seizure history, renal impairment, DIC or other coagulopathies, color vision disorders, pregnant/breastfeeding, heart failure/fluid restriction conditions, hyponatremia/history, revision surgeries, uncontrolled hypertension, significant coronary artery disease or arrhythmias.

Intervention groups

Patients will randomly assign to one of the three study groups: patients in the DDAVP group will receive 0.3 µg/kg of IV DDAVP preoperatively, 15 mg/kg of IV TXA in the TXA group, and 0.3 µg/kg of IV DDAVP + 15 mg/kg of IV TXA in the combination group.

Main outcome variables

Intraoperatively, the duration of surgery (minutes), and total suctioned blood volume (ml), will be recorded. We are also going to document, the surgical quality field score. Post-operatively any significant adverse .effects within 3 days including nausea, vomiting, epistaxis, and headache will be reported

General information

Reason for update

Acronym

TDEFECT (TXA, DDAVP Efficacy Functional Endoscopic Clinical Trial)

IRCT registration information

IRCT registration number: **IRCT20231112060028N1**
Registration date: **2023-11-15, 1402/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-15, 1402/08/24**
Update count: **0**

Registration date

2023-11-15, 1402/08/24

Registrant information

Name

Ali Faramarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-12, 1402/08/21

Expected recruitment end date

2024-11-11, 1403/08/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Intravenous Desmopressin, Tranexamic Acid, and their combination on intra-operative bleeding during functional endoscopic sinus surgery of adults

Public title

Intravenous Desmopressin, Tranexamic Acid, and Their Combined Impact on Intra-Operative Bleeding in Functional Endoscopic Sinus Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

First-time candidates of bilateral FESS due to chronic rhinosinusitis with polyp Patients should have a normal test result (CBC, PT, PTT, renal function tests, electrolytes) Patients classified as American Society of Anesthesiologists (ASA) I and ASA II

Exclusion criteria:

Wegener's disease Sarcoidosis Sinonasal malignancy Bleeding disorders Known hypersensitivity to TXA or DDAVP Active venous or arterial thromboembolic disease History of seizures Renal impairment (defined as a creatinine clearance below 50 mL/min) Disseminated Intravascular Coagulation (DIC) or any coagulopathy Color vision disorders Pregnancy and breastfeeding Heart failure or other conditions needing fluid restrictions Hyponatremia or history of hyponatremia Revision surgeries Poorly controlled hypertension or cerebrovascular disease History of significant coronary artery disease or arrhythmias

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method for this double-blinded randomized clinical trial will be conducted using computer-generated random numbers. The assignment of participants to the study groups will be performed in a randomized manner to ensure equal distribution among the groups. The randomization process will be carried out by an individual who is not directly involved in the recruitment or assessment of participants. Once informed consent is obtained from eligible participants, they will be assigned a unique identification number. The randomization list will be generated using a computer program, which will allocate participants to one of the ..three study groups: DDAVP group, TXA group, or combination group

Blinding (investigator's opinion)

Double blinded

Blinding description

To ensure the integrity and validity of the study, a double-blind approach will be implemented, where both the participants and the research team will be blinded to the treatment assignments. The blinding method will involve the following measures: 1. Blinded Treatment Allocation: The assignment of participants to the three study groups (DDAVP group, TXA group, and combination group) will be performed using computer-generated random numbers by an independent researcher not involved in the data collection or analysis. The treatment allocation will be concealed from the participants, surgeons, anesthesiologist, and other members of the research team who are directly involved in patient care. 2. Identical Packaging and Labeling: The DDAVP and TXA medications will be prepared and packaged in identical containers with matching labels. The containers will be indistinguishable in appearance, ensuring that neither the participants nor the healthcare providers can differentiate between the treatments. 3. Blinded Administration: The medications (DDAVP and TXA) will be administered intravenously by a nurse or healthcare provider who is not directly involved in the data collection or analysis. The administration will be performed in a separate room away from the surgical area, ensuring that the surgical team remains unaware of the specific treatment being administered. 5. Blinded Data Collection and Analysis: The collection of intraoperative and postoperative data, will be performed by research personnel who are blinded to the treatment assignments. These individuals will not have access to the treatment information during data collection, thereby preventing any potential bias in data recording. 5. Unblinding Procedures: In the case of an emergency or if there is a medical necessity to reveal the treatment assignment for a specific participant, a separate unblinding procedure will be established. This procedure will outline .the steps to be followed to maintain the blinding integrity of the study while addressing the participant's needs

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand St.
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2023-11-07, 1402/08/16
Ethics committee reference number
IR.SUMS.MED.REC.1402.360

Health conditions studied

1

Description of health condition studied
Chronic sinusitis
ICD-10 code
J32
ICD-10 code description
Chronic sinusitis

2

Description of health condition studied
Nasal polyp
ICD-10 code
J33
ICD-10 code description
Nasal polyp

Primary outcomes

1

Description
intra-operative blood loss
Timepoint
Intra-operative and at the end of the operation
Method of measurement
The volume of blood suctioned during the operation excluding the normal volume of saline used

2

Description
Surgical field bleeding score
Timepoint
Intraoperative
Method of measurement
BOEZAART grading scale for scoring surgical field bleeding

Secondary outcomes

1

Description
duration of surgery
Timepoint
At the end of the operation
Method of measurement
The end of the operation minus the start of the operation

Intervention groups

1

Description
Intervention group (Desmopressin Group): Patients will undergo general anesthesia and FESS as indicated under the routine standard of care. Patients in the DDAVP group will receive 0.3 µg/kg of IV DDAVP (DESMOPRESSIN INJECTION PARENTERAL 4 µg/1mL, Ferring GmbH, Switzerland), before the start of the operation.
Category
Treatment - Drugs

2

Description
Intervention group (Tranexamic Acid Group): Patients will undergo general anesthesia and FESS as indicated under the routine standard of care. Patients will receive before the operation, 15 mg/kg of IV TXA (TRANEXAMIC ACID INJECTION PARENTERAL 100 mg/1mL 5MILLILITER, Caspian Tamin Pharmaceutical Company, Iran) in the TXA group.
Category
Treatment - Drugs

3

Description
Intervention group (Desmopressin + Tranexamic Acid): Patients will undergo general anesthesia and FESS as indicated under the routine standard of care. Patients in the DDAVP group will receive the combination of 0.3 µg/kg of IV DDAVP (DESMOPRESSIN INJECTION PARENTERAL 4 µg/1mL, Ferring GmbH, Switzerland) and 15 mg/kg of IV TXA (TRANEXAMIC ACID INJECTION PARENTERAL 100 mg/1mL 5MILLILITER, Caspian Tamin Pharmaceutical Company, Iran), before the start of the operation in the combination group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dena Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
https://www.sums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mohammad Faramarzi, Ali Faramarzi, Arash Farbood
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
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Ali Faramarzi
Position
Research Assistant, Medical student
Latest degree
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is 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
The data that support the findings of this study include study outcomes of the data gathering form.
When the data will become available and for how long
The data will be available from Ali Faramarzi, upon reasonable request for journal peer-reviewers and editors during the publication process and for readers after publication upon reasonable request.
To whom data/document is available
It will be available from Ali Faramarzi, upon reasonable request for journal peer-reviewers and editors during the publication process and for readers after publication upon reasonable request.
Under which criteria data/document could be used
For reviewers of the journal for further review and for other researchers for future studies
From where data/document is obtainable
Ali Faramarzi, MD, Otolaryngology Research Center, Khalili Hospital, Department of Otolaryngology, Shiraz University of Medical Sciences, Shiraz, Iran. Email: ali_faramarzi@sums.ac.ir
What processes are involved for a request to access data/document
Reviewers and editors of the journal to whom the article was submitted. After the publication of the article, other researchers can send their request for access to the data for review by presenting their registered proposal to the plan administrators.
Comments