

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Dexmedetomidine versus Transaxamic acid on intraoperative bleeding during functional endoscopic sinus surgery: a triple-blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of Dexmedetomidine versus Transaxamic acid on intraoperative bleeding during functional endoscopic sinus surgery

##### Design

This is a triple-blind randomized clinical trial, in which 72 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible patients who are candidate for functional endoscopic sinus surgery referring to the Besat Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be triple-blinded so that neither patients nor the physician examining the patients or data analyzer will be aware of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 61 years, Chronic rhino sinusitis with or without polyposis, Candidate for functional endoscopic sinus surgery, Exclusion criteria: Coagulopathy disorders, Taking anticoagulant medication in the last 5 days, History of thromboembolism, Acute or chronic renal failure, Hepatic cirrhosis, Uncontrolled chronic diseases such as hypertension, diabetes, heart failure, Having cardiac stent, Pregnancy

##### Intervention groups

Intervention group 1: Transaxamic acid injection (manufactured by Caspian Pharmaceutical Co.) 11 mgr/kg by intravenous infusion within 15 minutes  
Intervention group 2: Dexmedetomidine injection (manufactured by Behestan Daru Pharmaceutical Co.) one micgr/kg by intravenous infusion within 15 minutes

##### Main outcome variables

Primary outcome: Intraoperative bleeding volume  
Secondary outcome: Hemodynamic changes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N390**

Registration date: **2021-04-18, 1400/01/29**

Registration timing: **prospective**

Last update: **2021-04-18, 1400/01/29**

Update count: **0**

##### Registration date

2021-04-18, 1400/01/29

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-11-21, 1400/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of Dexmedetomidine versus Transaxamic acid on intraoperative bleeding during functional endoscopic sinus surgery: a triple-blind randomized clinical trial

**Public title**

Effect of Dexmedetomidine versus Transaxamic acid on intraoperative bleeding during functional endoscopic sinus surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 18 to 61 years, Chronic rhino sinusitis with or without polyposis, Candidate for functional endoscopic sinus surgery,

**Exclusion criteria:**

Coagulopathy disorders, Taking anticoagulant medication in the last 5 days, History of thromboembolism, Acute or chronic renal failure, Hepatic cirrhosis, Uncontrolled chronic diseases such as hypertension, diabetes, heart failure, Having cardiac stent, Pregnancy

**Age**

From **18 years** old to **61 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The drugs will be given a code. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Thus, the trial will be run as triple-blind.

**Placebo**

Not 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 Sciences

**Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2020-06-13, 1399/03/24

**Ethics committee reference number**

IR.UMSHA.REC.1399. 298

**Health conditions studied****1****Description of health condition studied**

Chronic rhino sinusitis

**ICD-10 code**

J32

**ICD-10 code description**

Chronic sinusitis

**Primary outcomes****1****Description**

Intraoperative bleeding volume

**Timepoint**

At 15, 30, 60 and 90 minutes after the start of surgery

**Method of measurement**

Using a calibrated suction chamber after reducing the volume of normal saline

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

Hemodynamic changes

**Timepoint**

At 15, 30, 60 and 90 minutes after the start of surgery

**Method of measurement**

Using monitoring machine

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

Intervention group 1: Transaxamic acid injection (manufactured by Caspian Pharmaceutical Co.) 11 mgr/kg by intravenous infusion within 15 minutes

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: Dexmedetomidine injection (manufactured by Behestan Daru Pharmaceutical Co.) one micgr/kg by intravenous infusion within 15 minutes

**Category**

Treatment - Drugs

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

Besat Hospital in Hamadan city

**Full name of responsible person**

Dr Negar Ghaghi

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

negarhaghi27@yahoo.com

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

**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**

Dr Negar Ghaghi

**Position**

Resident of ENT

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

negarhaghi27@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Saeid Ahmadi

**Position**

ENT Specialist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

ahmadi@umsha.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of

Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

## 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**

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