Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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