Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Study on Effectivness of Topical Furesemaide 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
Determination of the effect of topical furesemaide on reducing bleeding and improving the quality of surgical field during endoscopic sinus surgery in patients with chronic rhinosinusitis

Design
double-blind randomized clinical trials with control group

Settings and conduct
This study is performed in the Besat hospital in Hamadan. All patients received a nasal spray twice a day, one week before surgery , in the case group Topical Furesemaide and normal saline in the control group. The bottles containing the Topical Furesemaide and saline are completely identical and are identified by the A and B codes, respectively. P. Quality of field of vision at the end of surgery based on Boezaart Grading as well as intraoperative bleeding is recorded. For the purpose of blindness, given that the saline solution is poured into the spray container in a manner similar to that of the Topical Furesemaide solution (by the pharmacy technician), the patient and surgeon will not be aware of the spray content used(double-blind).

Participants/Inclusion and exclusion criteria
Participants: Patients undergoing endoscopic sinus surgery Inclusion criteria: age 18 to 60 years and PT, PTT, INR, BT, CT Exclusion criteria .history of bleeding disorders ,uncontrolled acute or chronic renal failure, Receive heparin 48 hours before surgery and aspirin within 3 days before surgery and Allergies to furesemaide

Intervention groups
Intervention group: Patients are candidates for endoscopic sinus surgery one week before surgery Treated with nasal furazide nasal spray at a dose of 20 µg twice daily. Control group: Patients are candidates for endoscopic sinus surgery one week before surgery Treat with placebo nasal spray twice daily.

Main outcome variables
amount of Bleeding during surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151123025202N3**
Registration date: **2019-11-23, 1398/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-23, 1398/09/02**
Update count: **0**

Registration date
2019-11-23, 1398/09/02

Registrant information

Name
Abbas Moradi

Name of organization / entity
Hamedan University of Medical Of Science

Country
Iran (Islamic Republic of)

Phone
+98 81 3838 0097

Email address
a.moradi@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on Effectivness of Topical Furesemaide administration on intraoperative blood loss and quality of the surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis

Public title

Effectivness of Topical Furesemaide chronic on rhinosinusitis surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic rhinosinusitis with or without polyposis (primary or recurrent) Ages between 18 and 60 years Normalization of PT, PTT, INR, BT, CT and platelet count

Exclusion criteria:

have Bleeding disorders such as uncontrolled hemophilia Uncontrolled history of thromboembolic events Uncontrolled Receive heparin at 48 hours before surgery ake aspirin within 3 days before surgery Allergies to Furesemaide Liver Cirrhosis Systemic diseases such as hypertension, diabetes, heart failure Patients with sinonasal tumor side effects of Furesemaide acute or chronic renal failure Cardiac stent

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **72**

More than 1 sample in each individual

Number of samples in each individual: **36**

36 patients in the intervention group received Topical Furesemaide and 36 in the control group receiving normal saline drops.

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, hexagonal block randomization is used. Hence, six sheets of paper were prepared and written on the three letters A (Intervention group) and on the other three letters B (control group). Each patient was randomly assigned to one of the two intervention or the control . Recipients of nasal spray will be assigned. It should be noted that the sheets were drawn until all six sheets were removed to the drawer. After randomly pulling out all six sheets, all sheets will be returned to the drawer again and the operation will be continued for the next six patients until the desired sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug and placebo containers will be designed and coded in the same fashion by the pharmacist. The patient will not be aware of the spray content used. Also, the surgeon who will measure and record the outcome of the study will not be aware of the spray content used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Hamedan University of medical science

Street address

shahid fahmide Ave

City

Hamedan

Province

Hamadan

Postal code

6517838677

Approval date

2019-09-28, 1398/07/06

Ethics committee reference number

IR.UMSHA.REC.1398.518

Health conditions studied

1

Description of health condition studied

chronic rhino sinusitis

ICD-10 code

Js32.9

ICD-10 code description

js32.9

Primary outcomes

1

Description

reduce bleeding in surgery site

Timepoint

end of surgery time

Method of measurement
The amount of blood collected in the suction bottle (after deduction of normal saline volume) and the weight of blood-stained packs

Secondary outcomes

1

Description
Quality of vision of the surgical field
Timepoint
during the surgery
Method of measurement
with Boezaart Grading questionair

Intervention groups

1

Description
Intervention group: receive one Puff of Furzemide spray (20 micrograms per puff equivalent to 40 micrograms) in each nasal side daily from one week before surgery.
Category
Treatment - Drugs

2

Description
Control group: receive one Puff of normal saline in each nasal side daily from one week before surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
dr Javane Jahanshahi
Street address
shahid Beheshti Blvd
City
Hamedan
Province
Hamadan
Postal code
6515974544
Phone
+98 81 3264 0030
Fax
+98 81 3265 1515
Email
Besat@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
dr Saeid Bashirian
Street address
Shahid Fahmide Ave
City
Hamedan
Province
Hamadan
Postal code
6517838677
Phone
+98 81 3838 0717
Fax
+98 81 3838 0130
Email
vc_research@umsha.ac.ir
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
Abbass Moradi
Position
empolye
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
No 5 Fath, Pirouzi, Ammar
City
Hamedan
Province
Hamadan

Postal code
6515974544
Phone
+98 81 3823 5480
Email
a.moradi@umsha.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Javane Jahanshahi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Shahid Fahmideh Ave
City
Hamedan
Province
Hamadan
Postal code
6517838677
Phone
+98 81 3838 0097
Email
jahanshahi287@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Abbas Moradi
Position
Staff on community medicine
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
Shahid Fahmideh
City
hamedan
Province
Hamadan
Postal code
6517838677
Phone
+98 81 3838 0097
Email
a.moradi@umsha.ac.ir

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
No - There is not 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
The data on the method of work and the outcome of the intervention can be shared
When the data will become available and for how long
After the end of the study and for an unlimited period
To whom data/document is available
Medical students and graduates
Under which criteria data/document could be used
For study and publication with citation and meta-analysis studies
From where data/document is obtainable
refer to Scientific responsible
What processes are involved for a request to access data/document
Submit request by email address listed
Comments