

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Study on Effectiveness of Topical Furosemide 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 furosemide 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 Furosemide and normal saline in the control group. The bottles containing the Topical Furosemide 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 Furosemide 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 furosemide

Intervention groups

Intervention group: Patients are candidates for endoscopic sinus surgery one week before surgery Treated with nasal furosemide 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)

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

Public title
Effectiveness of Topical Furosemide 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 take aspirin within 3 days before surgery Allergies to Furosemide Liver Cirrhosis Systemic diseases such as hypertension, diabetes, heart failure Patients with sinonasal tumor side effects of Furosemide 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 Furosemide 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

J32.9

ICD-10 code description

J32.9

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

dr Saeid Bashirian

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Staff on community medicine
Latest degree
Master
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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