

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of infiltration of pterygopalatine fossa with lidocaine and epinephrine solution on intraoperative bleeding during endoscopic sinonasal surgeries in chronic sinusitis patients attending Amir-Almomenin hospital in Rasht

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect of infiltration of pterygopalatine fossa with lidocaine and epinephrine solution on intraoperative bleeding during endoscopic sinonasal surgeries in chronic sinusitis patients

Last update: **2021-05-09, 1400/02/19**

Update count: **0**

Registration date

2021-05-09, 1400/02/19

Design

Double blind randomized clinical trial by block randomization via sealed envelope software for outcome assessment

Registrant information

Name

Sevil Nasirmohtaram

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

Chronic rhinosinusitis patients attending Amir-almomenin hospital during 2021 candidate for endoscopic sinus surgery will be assessed for bleeding during surgery after infiltration of pterygopalatine fossa. Patients, surgeon and questionnaire filler are blind for the solution contents.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Chronic rhinosinusitis patients with and without polyposis, who are 18-65 years old and are candidate for endoscopic sinus surgery after maximal medical therapy are included

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Study group would be the side infiltrated by lidocaine and epinephrin solution in pterygopalatine fossa, in control side normal saline would be injected.

Main outcome variables

Blood volume during surgery Surgical field grading using Boezaart scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210307050609N1**

Registration date: **2021-05-09, 1400/02/19**

Scientific title

The effect of infiltration of pterygopalatine fossa with lidocaine and epinephrine solution on intraoperative bleeding during endoscopic sinonasal surgeries in chronic sinusitis patients attending Amir-Almomenin

hospital in Rasht

Public title

The effect of infiltration of pterygopalatine fossa with lidocaine and epinephrine solution on intraoperative bleeding during endoscopic sinonasal surgeries in chronic sinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic sinusitis with or without polyposis with symmetric disease on both sides, candidate for endoscopic sinus surgery after maximal medical treatment, are included.

Exclusion criteria:

History of coagulopathies, strict indication to use anti-coagulant drug, history of dysrhythmia or cardiac disease, history of lidocaine sensitivity, patients candidate for unilateral surgery, history of garlic, ginseng, vitamin E or fish oil consumption in recent 2 weeks

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients would be randomly classified as intervention and control group with block randomization in 10 blocks of 4 by allocating a specific code number using Sealed Envelope software.

Blinding (investigator's opinion)

Double blinded

Blinding description

patient is unaware of placebo or drug side surgeon, clinician who fulfills the operative checklist, and data analyzer are all blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Gilan University of Medical Sciences

Street address

NO. 17,108 Ave., Golsar Blvd., Rasht, Gilan

City

Rasht

Province

Guilan

Postal code

4165755199

Approval date

2021-02-17, 1399/11/29

Ethics committee reference number

IR.GUMS.REC.1399.606

Health conditions studied

1

Description of health condition studied

surgical field blood using Beozaart scale

ICD-10 code

ICD-10 code description

2

Description of health condition studied

intraoperative blood volume assessed by estimating blood volume in the bottle and number of cotton bands soaked in blood

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intraoperative bleeding

Timepoint

Every 15 minutes during surgery

Method of measurement

Boezaart scale and blood volume in milliliter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: after induction of general anesthesia 2 cc of lidocain plus epinephrin solution in injected into pterygopalatine fossa through greater palatin foramen with an angle of 45 degrees

Category

Treatment - Drugs

2**Description**

Control group: :ion group after induction of general anesthesia 2 cc of normal saline solution in injected into pterygopalatine fossa through greater palatin foramen with an angle of 45 degrees

Category

Placebo

Recruitment centers1**Recruitment center****Name of recruitment center**

Amir-almomenin hospital

Full name of responsible person

Sevil Nasirmohtaram

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Sevil Nasirmohtaram

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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

Rasht University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

after hiding personal data of patients it is possible

When the data will become available and for how long

6 months after publishing data

To whom data/document is available

researchers and scientific and academic organs

Under which criteria data/document could be used

exclusively for scientific reasons

From where data/document is obtainable

corresponding writer

What processes are involved for a request to access data/document

It can be accessed during 1 month from sending a letter through email, after brief explanation about reason of request and scientific position of writer

Comments