

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Investigating the effect of Oxymetazoline nasal spray on septorhinoplasty surgery bleeding

Protocol summary

Study aim

Comparison of the amount of bleeding during septorhinoplasty in the group receiving Oxymetazoline nasal spray compared to the control group without receiving Oxymetazoline nasal spray.

Design

Randomized controlled, parallel-group, unblinded, phase 2-3 clinical trial on 30 patients. The randomization method will be "Random Allocation" computer software.

Settings and conduct

The statistical population in this study consists of patients who are candidates for septorhinoplasty surgery who visited the Arad Ardabil surgery center between July 2023 and the end of December 2023 and underwent surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria included being a candidate for septorhinoplasty surgery, ASA one or two, and having consent to participate in the study. Exclusion criteria include having sensitivity to Oxymetazoline.

Intervention groups

For patients in the case group, two puffs of Oxymetazoline nasal spray will be used 5 minutes before the start of septorhinoplasty, while in the control group, no intervention was performed and they will be under routine care.

Main outcome variables

Patient's gender, patient's age, surgeon's satisfaction with the surgical field, patients' systolic and diastolic blood pressure before induction of anesthesia and after intubation and at the end of surgery, heart rate, bleeding rate, use of secondary antihypertensive drugs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230514058190N1**

Registration date: **2023-06-25, 1402/04/04**

Registration timing: **prospective**

Last update: **2023-06-25, 1402/04/04**

Update count: **0**

Registration date

2023-06-25, 1402/04/04

Registrant information

Name

Hossein Farzaneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3372 1255

Email address

hossein.frz96@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2023-12-31, 1402/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Oxymetazoline nasal spray on septorhinoplasty surgery bleeding

Public title

Effect of Oxymetazoline on septorhinoplasty surgery bleeding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for septorhinoplasty surgery ASA one or two

Consent to participate in the study

Exclusion criteria:

Being allergic to Oxymetazoline

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

30 eligible patients will be selected randomly. Then these people will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of two intervention and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Islamic Azad University- Ardabil Branch

Street address

Basij square

City

Ardabil

Province

Ardabil

Postal code

5615731567

Approval date

2023-02-07, 1401/11/18

Ethics committee reference number

IR.IAU.ARDABIL.REC.1402.003

Health conditions studied

1

Description of health condition studied

Bleeding in septorhinoplasty surgery

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

Primary outcomes

1

Description

Bleeding rate

Timepoint

During septorhinoplasty surgery

Method of measurement

Measuring the blood in the suction device

2

Description

Systolic and diastolic blood pressure

Timepoint

Before induction of anesthesia, after intubation and at the end of surgery

Method of measurement

Monitoring device

3

Description

Heart rate

Timepoint

Before induction of anesthesia, after intubation and at the end of surgery

Method of measurement

Monitoring device

Secondary outcomes

1

Description

Surgeon's satisfaction with the surgical field

Timepoint

After completion of septorhinoplasty surgery

Method of measurement

According to the opinion of the surgeon who performed the septorhinoplasty surgery

Intervention groups

1

Description

Intervention group: For patients in the case group, two puffs of Oxynose Nasal Spray made by Raha Pharmaceutical Company, which contains Oxymetazoline

Hydrochloride 0.05%, will be used 5 minutes before the start of septorhinoplasty.

Category

Prevention

2

Description

Control group:In the control group, no intervention will be done and they will be under routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Arad Ardabil Surgery Center

Full name of responsible person

Dr.Raof Mollajavadi

Street address

Motahari street, Yahyavi square

City

Ardabil

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5613943311

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mollajavadi.r@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Raof Mollajavadi

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Hossein Farzaneh

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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No.103, North Hojati alley ,16 meter Omid street, Hafez street

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hossein.frz96@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Raof Mollajavadi

Position

Non-academic specialist doctor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Hossein Farzaneh
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
No.103, North Hojati alley ,16 meter Omid street,
Hafez street
City
Ardabil
Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The majority of participants agreed to participate if the confidentiality of data would be guaranteed, given the type of surgery they would undergo.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available