

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of not injecting lidocaine on the bleeding rate during open rhinoplasty

Protocol summary

Study aim

Determining the amount of bleeding during rhinoplasty surgery after not injecting lidocaine

Design

Two arm ;parallel group; randomised trial;phase 1; 42 patients; table of random numbers is used for randomization.

Settings and conduct

1- The place of study: plastic surgery department of Imam Khomeini Hospital and Amir Alam Hospital in Tehran 2- The study population: All referring patients at the age range of 18 and 30 years for open rhinoplasty 3- Blinding: there won't be blinding in this study

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients referred for open rhinoplasty surgery; Patients between the ages of 18 and 30. Non-Inclusion criteria: coagulation and platelet disorder; broken nose; allergy to lidocaine; high blood pressure; smoking.

Intervention groups

Intervention group: In this group, only 1/100000 epinephrine solution with a volume of 10 cc is injected in the nasal surgery field. Control group: In this group, 100000/1 epinephrine solution along with 1% lidocaine with a volume of 10 cc is injected in the nasal surgery field.

Main outcome variables

The amount of bleeding during rhinoplasty surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230508058122N1**

Registration date: **2023-07-01, 1402/04/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-01, 1402/04/10**

Update count: **0**

Registration date

2023-07-01, 1402/04/10

Registrant information

Name

Hesamodin Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2213 3414

Email address

hesam154982p@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-24, 1402/04/03

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of not injecting lidocaine on the bleeding rate during open rhinoplasty

Public title

The effect of not injecting lidocaine on the bleeding rate of open rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients referred for open rhinoplasty surgery Age range of 18 to 30 years

Exclusion criteria:

Coagulopathy Nasal bone fracture Hypersensitivity reaction to lidocaine Smoking Hypertension

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the table of random numbers and considering that the sample size in this study is 42 patients, each patient is given a 2-digit code. (01, 02, 03, 04 and...) To select sample people from the table, randomly start from a point of the table in the direction of the row or column of two-digit numbers, and the selection of the point is done by closing the eyes and placing a finger or the tip of the pen on the table. Movement does not differ in row or column direction The selected number is actually the code of an individual from the community that is selected as a sample. This work continues until the number of sample people can be selected. After the sample volume is complete, the sampling work ends.

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Baqerkhan Street, Imam Khomeini Hospital

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-06-21, 1402/03/31

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.103

Health conditions studied

1

Description of health condition studied

Open rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

the amount of bleeding during rhinoplasty

Timepoint

At the end of surgery

Method of measurement

Bleeding volume in cc

Secondary outcomes

1

Description

Eye ecchymosis

Timepoint

The first day after surgery

Method of measurement

Gurlec criterion

2

Description

The quality of the surgical field

Timepoint

During surgery

Method of measurement

Boezaart criterion

3

Description

Surgeon satisfaction

Timepoint

During surgery

Method of measurement

Likert criterion

Intervention groups

1

Description

Intervention group: In this group, epinephrine solution with a concentration of 1.100000with a volume of 10 cc is injected in the nasal surgical field at the beginning of the surgery.

Category

Treatment - Drugs

2**Description**

Control group: In this group, epinephrine solution with a concentration of 1.100000 along with lidocaine with a concentration of 1% with a volume of 10 cc is injected at the beginning of the surgery in the nasal surgery field

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini hospital

Full name of responsible person

Hesamodin Karimi

Street address

Baqerkhan Street

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119

Email

Imamhospital@tums.ac.ir

2**Recruitment center****Name of recruitment center**

Amiralam hospital

Full name of responsible person

Hesamodin Karimi

Street address

Saadi street

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Province

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Postal code

1145765111

Phone

+98 21 6634 3352

Email

hamiralam@sina.tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotuhi

Street address

baqerkhan

City

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Postal code

1419733141

Phone

+98 21 6119

Email

Imamhospital@tums.ac.ir

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

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Hesamodin Karimi

Position

Assistant of plastic surgery subspecialty course

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imamkhomeini hospital; Baqerkhan Street

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Province

Tehran

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1419733141

Phone

+98 21 2283 3414

Email

hesam154982p@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hesamodin Karimi

Position

Assistant of plastic surgery subspecialty course

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

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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

Privacy protection

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