

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Investigating the effect of subcutaneous tranexamic acid injection on the amount of bleeding in rhinoplasty surgery under general anesthesia.

Protocol summary

Study aim

Investigating the effect of subcutaneous tranexamic acid injection on the amount of bleeding in rhinoplasty surgery under general anesthesia.

Design

A clinical trial with a control group, phase 2-3 on 60 patients to investigate the amount of bleeding during rhinoplasty with and without tranexamic acid injection.

Settings and conduct

This study is conducted in 2022 at Al-Zahra Hospital in Isfahan on 60 patients who are candidates for rhinoplasty surgery. Within 60 minutes from the start of surgery and every 10 minutes during the first 20 minutes of recovery, the amount of bleeding in the two groups of patients is measured and compared by a suction device.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-50 years, candidate for rhinoplasty, having a score of 1 or 2 according to the American Society of Anesthesiologists and signing a written informed consent to participate in this study. Exclusion criteria: uncontrolled systemic disease, history of malignant hyperthermia, refusal to continue participating in the study and occurrence of any complications during surgery.

Intervention groups

Intervention group: Patients in this group, during anesthesia, receive 10 cc of a solution that contains 5 cc of a solution containing half percent lidocaine and epinephrine (1 in four hundred thousand) and 5 cc of 10 percent tranexamic acid. Control group: Patients in this group, during anesthesia, receive 10 cc of a solution containing half percent lidocaine and epinephrine (one in two hundred thousand). The bleeding rate of patients is measured and compared at the end of surgery.

Main outcome variables

Bleeding.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051574N14**

Registration date: **2022-09-28, 1401/07/06**

Registration timing: **prospective**

Last update: **2022-09-28, 1401/07/06**

Update count: **0**

Registration date

2022-09-28, 1401/07/06

Registrant information

Name

Ghasem Mohammadsharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3729 4005

Email address

mohammadsharifi.ghasem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-05, 1401/08/14

Expected recruitment end date

2023-01-04, 1401/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of subcutaneous tranexamic acid injection on the amount of bleeding in rhinoplasty surgery under general anesthesia.

2021-12-24, 1400/10/03

Ethics committee reference number
IR.MUI.MED.REC.1400.709

Public title

Tranexamic acid on bleeding rate in rhinoplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 50 years Candidate for rhinoplasty Having a score of 1 or 2 based on the American Society of Anesthesiologists Signing the written informed consent to participate in this study

Exclusion criteria:

Uncontrolled systemic disease History of malignant hyperthermia Refusing to continue participating in the study Incidence of any complication during surgery

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

Health conditions studied

1

Description of health condition studied

Bleeding

ICD-10 code

D78.22

ICD-10 code description

Postprocedural hemorrhage and hematoma of the spleen following other procedure

Primary outcomes

1

Description

Bleeding volume

Timepoint

Within 60 minutes from the start of surgery and every 10 minutes during the first twenty minutes of recovery

Method of measurement

Suction device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group, during anesthesia, receive 10 cc of a solution that contains 5 cc of a solution containing half percent lidocaine and epinephrine (1 in four hundred thousand) and 5 cc of 10 percent tranexamic acid. The bleeding rate of patients is measured and compared at the end of surgery.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group, during anesthesia, receive 10 cc of a solution containing half percent lidocaine and epinephrine (one in two hundred thousand). The bleeding rate of patients is measured and compared at the end of surgery.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Hamid Shetabi

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0042

Email

parsa.alinezhad85@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

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Phone

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haghjoo.sh@med.mui.ac.ir

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hamid Shetabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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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

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Send a message to the mentioned e-mail address

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

E-mail the responsible person and if you accept the conditions, the information will be sent.

Comments