

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparative study of the effects of clonidine and tranexamic acid on the rate of bleeding during rhinoplasty surgery. Clinical trial

Protocol summary

Study aim

Comparative study of the effects of clonidine and tranexamic acid on the rate of bleeding during rhinoplasty surgery

Design

This study is a randomized double-blind clinical trial with a parallel design. This randomized study will be conducted on 92 patients who are candidates for rhinoplasty surgery. A simple random method is used for randomization and the participants are assigned to two intervention groups.

Settings and conduct

This study, which will be conducted at Imam Reza Hospital in Kermanshah, is double-blind. The outcome assessor and the participants are blinded to the study group allocation. Before surgery, venous access is established for all patients, and routine monitoring of the operating room, including non-invasive blood pressure measurement, ECG monitoring, and pulse oximetry, is performed by the anesthesia team.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Age between 18-60 years
Exclusion criteria: Addiction to narcotics and benzodiazepines
History of seizures; Suffering from liver and kidney failure, diabetes, lung and heart diseases, and coagulation disorders; History of allergy to clonidine and tranexamic acid drugs

Intervention groups

The first intervention group will receive 700 micrograms of tranexamic acid per kilogram of body weight orally two hours before surgery. The second intervention group will receive 2 micrograms of clonidine per kilogram orally 90 minutes before surgery.

Main outcome variables

Bleeding rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N211**
Registration date: **2023-11-25, 1402/09/04**
Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effects of clonidine and tranexamic acid on the rate of bleeding during

rhinoplasty surgery. Clinical trial

Public title

Comparison of the effects of clonidine and tranexamic acid on the rate of bleeding during nose surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Age between 18-60 years

Exclusion criteria:

Addiction to narcotics and benzodiazepines History of seizures Suffering from liver and kidney failure, diabetes, lung and heart diseases, coagulation disorders History of allergy to clonidine and tranexamic acid drugs pregnancy

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in a simple random method, after identifying eligible patients, they will be randomly assigned a three-digit dedicated code. The last digit on the right determines the patient group. If this number is 0, 1, 2, 3, 4, it will be assigned in the first intervention group, and if this number is 5, 6, 7, 8, 9, it will be assigned in the second intervention group

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, the patients are aware of their participation in the study and receiving the medication, but the outcome evaluator is blinded to the allocation of the study groups and the medication they received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2023-09-03, 1402/06/12

Ethics committee reference number

IR.KUMS.MED.REC.1402.172

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

M95.0

ICD-10 code description

Acquired deformity of nose

Primary outcomes

1

Description

Bleeding rate

Timepoint

The beginning of the study and the end of the study

Method of measurement

Based on the amount of blood collected in the suction

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive 700 micrograms of tranexamic acid per kilogram of body weight orally two hours before surgery

Category

Treatment - Drugs

2

Description

The second intervention group will receive 2 micrograms of clonidine per kilogram orally 90 minutes before surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Maryam safdari

Street address

Emam Reza Hospital, Parastar Boulevard

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6715847141

Phone

+98 83 3427 6306

Email

sainasfd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Cyrus Jalili

Street address

Vice Chancellor for Research Affairs, Kermanshah
University of Medical Sciences, Building No.2, Shahid
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cjalili@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Maryam safdari

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Bagher Heydari

Position

Member of the academic staff of Kermanshah
University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Plastic Surgery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Maryam Safdari

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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

There is no further information

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