Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
City
Kermanshah
Province
Kermanshah
Postal code
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 Beheshti Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3836 0014
Email
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
Street address
Emam Reza Hospital, Parastar Boulevard
City
kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
sainasfd@gmail.com

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
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
sainasfd@gmail.com

Person responsible for updating data

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
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
sainasfd@gmail.com

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