

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of four drugs clonidine, bisoprolol, tranexamic acid and gabapentin on bleeding rate, hemodynamic stability and intraoperative surgeon satisfaction in patients undergoing rhinoplasty surgery.

Protocol summary

Study aim

Comparison of four drugs clonidine, bisoprolol, tranexamic acid and gabapentin on bleeding rate, hemodynamic stability and intraoperative surgeon satisfaction

Design

This study will be a double-blind randomized clinical trial with parallel groups on 75 patients referred to Motahhari Hospital in Jahrom who undergo rhinoplasty surgery. In this study, computerized block randomization (13 blocks of 10) will be performed. An independent epidemiologist who is not involved in the study will use a random blockchain program (SATA14) to generate allocation codes. Random sequences will be placed in light-resistant and sealed envelopes. The research assistant will open sealed, numbered, and opaque envelopes containing the assignment codes.

Settings and conduct

Patients referred to Motahhari Hospital in Jahrom who will undergo rhinoplasty surgery will be included in the study. Patients participating in the study will be divided into five groups by throwing dice: clonidine, bisoprolol, gabapentin, tranexamic acid and control. The person participating in the study, the researcher and the data collector will be unaware of the type of drug used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients referred to Motahhari Hospital in Jahrom who underwent rhinoplasty and expressed their consent to participate in the study. Exclusion criteria : includes patients who do not have hemodynamic stability.

Intervention groups

Intervention group 1: They will receive clonidine / 2 mg intravenously. Intervention group 2: They will receive 5.2 mg bisoprolol tablets. Intervention group 3: They will receive 4 capsules gabapentin 300 mg . The intervention group 4: They will receive 4 capsules of 250 mg

tranexamic acid. Intervention group 5: They will receive a placebo as a control group.

Main outcome variables

Bleeding, hemodynamic stability and surgical surgeon satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050976N11**

Registration date: **2022-05-05, 1401/02/15**

Registration timing: **prospective**

Last update: **2022-05-05, 1401/02/15**

Update count: **0**

Registration date

2022-05-05, 1401/02/15

Registrant information

Name

navid kalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 6085

Email address

k.navid@juma.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-10, 1401/02/20

Expected recruitment end date

2022-09-01, 1401/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of four drugs clonidine, bisoprolol, tranexamic acid and gabapentin on bleeding rate, hemodynamic stability and intraoperative surgeon satisfaction in patients undergoing rhinoplasty surgery.

Public title

Comparison of four drugs clonidine, bisoprolol, tranexamic acid and gabapentin on bleeding rate, hemodynamic stability and intraoperative surgeon satisfaction in patients undergoing rhinoplasty surgery.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hemoglobin above 10 Lack of sensitivity to the drugs used

Exclusion criteria:

Patients with coagulation disorders Blood pressure
Coronary artery disease

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, computerized block randomization (13 blocks of 10) will be performed. An independent epidemiologist who is not involved in the study will use a random blockchain program (SATA 14) to generate allocation codes. Eligible participants, after signing the informed consent form, will be divided into five equal groups: clonidine, bisoprolol, gabapentin, tranexamic acid and placebo. Random sequences will be placed in light-resistant and sealed envelopes. The research assistant will open sealed, numbered, and opaque envelopes containing the assignment codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding in the present study, the double-blind method is used, so that 1- the person who reviews the results and 2- the person who performs the injections do not know which patient has received clonidine, bisoprolol, gabapentin, tranxamic acid and Placebo

only. The drugs Clonidine, bisoprolol, gabapentin, tranexamic acid, and placebo will be packaged in identical glass (two groups of clonidine and bisoprolol, which are in the form of tablets, are powdered and then placed in capsules. The capsules will be the same in all 5 groups) and given to the prescriber, and will be placed in the drug or placebo group, according to a random list, and the glass will be marked A, B, C, D, E will be given to the patient and the patient will be unaware of the type of medicine used.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Jahrom University of Medical Sciences

Street address

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

City

Shiraz

Province

Fars

Postal code

7167758256

Approval date

2022-01-11, 1400/10/21

Ethics committee reference number

IR.JUMS.REC.1400.072

Health conditions studied**1****Description of health condition studied**

Rhinoplasty surgery

ICD-10 code

Rhinoplast

ICD-10 code description

Rhinoplasty surgery

Primary outcomes**1****Description**

Blood pressure

Timepoint

Before induction, after induction, 1 minute after induction, 5 minutes after induction, 30, 60, 90 and 120

minutes during operation, enter recovery and exit recovery

Method of measurement

Monitoring

2

Description

Surgeon Satisfaction

Timepoint

During the operation every 15 minutes after the start of surgery and at the end of the operation

Method of measurement

Beozaart Scale

3

Description

Bleeding

Timepoint

During the operation

Method of measurement

The amount of bleeding in the suction in milliliters

Secondary outcomes

1

Description

Relaxation

Timepoint

In recovery

Method of measurement

Ramsey sedation criteria

Intervention groups

1

Description

Intervention group 1: They will receive clonidine 0/2 mg intravenously.

Category

Treatment - Drugs

2

Description

Intervention group 2: They will receive 5.2 mg bisoprolol tablets.

Category

Treatment - Drugs

3

Description

Intervention group 3: They will receive 4 capsules of gabapentin 300 mg .

Category

Treatment - Drugs

4

Description

Intervention group 4: They will receive 4 capsules of 250 mg tranexamic acid.

Category

Treatment - Drugs

5

Description

Control group: Placebo will normally receive intravenous saline.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital of Jahrom city

Full name of responsible person

Navid Kalani

Street address

Jahrom, Shahid Motahari Boulevard, Motahari Hospital

City

Jahrom

Province

Fars

Postal code

71677251542

Phone

+98 71 3525 5652

Email

Navidkalani@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Solh Joo Kavous

Street address

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

City

Jahrom

Province

Fars

Postal code

7167758256

Phone

+98 71 2536 5231

Email

navidkalani@ymail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jahrom 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**

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Jahrom, Shahid Motahari Boulevard

City

Jahrom

Province

Fars

Postal code

7167758256

Phone

+98 71 2536 5231

Email

k.navid@jums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Jahrom, Shahid Motahari Blvd., University of Medical Sciences

City

Jahrom

Province

Fars

Postal code

71542585125

Phone

+98 71 2536 5231

Email

k.navid@jums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Jahrom, Shahid Motahari Boulevard

City

Jahrom

Province

Fars

Postal code

7167758256

Phone

+98 71 2536 5231

Email

k.navid@jums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available