Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of Clonidine and Tranexamic Acid on the volume of bleeding during rhinoplasty under general anesthesia: clinical trial

Protocol summary

Study aim

Comparison of the Effect of Clonidine and Transxamic Acid on Bleeding During Rhinoplasty Under General Anesthesia

Design

This is a double blind clinical trial with a control group. The groups are divided into two groups (case group 90) and a control group (45 people) in a parallel randomized quadruple randomization method.

Settings and conduct

Preoperative surgery in Khatam Al-anbiya hospital in Shoushtar city will be established for all patients with intravenous tract. In the first group (clonidine group), clonidine 3 micrograms per kilogram will be given orally 90 minutes before surgery. In the second group (the Tranexamic Acid group), the Tranexamic Acid capsule 250 micrograms will be administered orally to patients two hours before the surgery.There will be no intervention in the control group. In this study, the volume of bleeding will be calculated based on the amount of blood collected and the blood-stained gases that will be weighed and the surgeon's vision.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate in research; aged between 18-60 years; classification of American Society of Anesthesiology in Class I and II. Exit criteria: Drug addiction, benzodiazepines, liver and kidney failure, diabetes, pulmonary and heart disease, coagulation disorders; history of hypersensitivity to clonidine and tranxacic acid.

Intervention groups

In the first group (Clonidine group), 3 micro grams per kilogram will be given orally 90 minutes before surgery. In the second group (the Tranexamic Acid group), the 250 mg Tranexamic Acid capsule will be administered orally for patients 2 hours before the surgery.

Main outcome variables

Amount of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121229011923N6**
Registration date: **2019-02-18, 1397/11/29**
Registration timing: **prospective**

Last update: **2019-02-18, 1397/11/29**
Update count: **0**

Registration date

2019-02-18, 1397/11/29

Registrant information

Name

Akram Hematipour

Name of organization / entity

Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Clonidine and Tranexamic Acid on the volume of bleeding during rhinoplasty under general anesthesia: clinical trial

Public title

Comparison of the efficacy of Clonidine and Tranexamic Acid on the volume of bleeding during rhinoplasty under general anesthesia: clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious willingness to participate in research Age between 18-60 years Classification of the American Society of Anesthesiology in Class I and II: Class 1: includes patients with normal health who have no systemic problems, such as cardiovascular, respiratory, gastrointestinal, etc. Class 2: Includes a person with mild systemic disease and disease Is under control and has not caused any limitation for the patient)

Exclusion criteria:

Drug addiction, benzodiazepines, liver and kidney failure, diabetes, pulmonary and heart disease, coagulation disorders; History of hypersensitivity to clonidine and Tranexamic Acid (increased blood pressure)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

135 people will be selected based on the formula for comparison of the meanings and randomly divided randomly into two groups of case (90) and a control group (45 people) based on the randomized quadruple randomization method. Then, the patients in the case group will be divided into two groups of Clonidine and Tranexamic Acid (45) and (45) by the reviewer, who will code the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients and the ENT surgeon will be unaware of the patient's group and the drugs. Only the investigator responsible for the study who is involved in the classification of the patients is aware.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shoushtar University of Medical Sciences

Street address

Shoushtar University of Medical Sciences, West Rajaee Crossroads

City

Shoushtar

Province

Khouzestan

Postal code

6451984381

Approval date

2019-01-14, 1397/10/24

Ethics committee reference number

IR.SHOUSHTAR.REC.1397.007

Health conditions studied

1

Description of health condition studied

Evaluation of bleeding during nasal surgery

ICD-10 code

Y44.2

ICD-10 code description

Anticoagulants

Primary outcomes

1

Description

Evaluation of bleeding during nasal surgery

Timepoint

During and after nose surgery

Method of measurement

The size of the bleeding will be calculated based on the amount of bleeding accumulated in the suction and the blood-stained gases that will be weighed and the surgeon's vision.

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: clonidine 3 micrograms per kilogram will be given orally 90 minutes before the surgery, and the amount of bleeding will be examined during surgery.
Category
Treatment - Drugs

2

Description
Second intervention group: Tranexamic Acid capsule 250 micrograms per kilogram body weight will be given to patients twice a day before surgery and the volume of bleeding will be examined during surgery.
Category
Treatment - Drugs

3

Description
Control group: The amount of bleeding will be checked without clonidine and Tranexamic Acid medications.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Al-anbia Hospital in Shoushtar
Full name of responsible person
Akram Hemmatipour
Street address
Khatam Al-anbia Hospital, Ammar Street
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6451984381
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hematipour.a64@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shoushtar University of Medical Sciences
Full name of responsible person
Dr Mojtaba Kalantar
Street address
Shoushtar University of Medical Sciences, West Rajaee Crossroads
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shoushtar 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
Shoushtar University of Medical Sciences
Full name of responsible person
Akram Hemmatipour
Position
University professor
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

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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
I do not know

When the data will become available and for how long
I do not know

To whom data/document is available
I do not know

Under which criteria data/document could be used
I do not know

From where data/document is obtainable
I do not know

What processes are involved for a request to access data/document
I do not know

Comments