Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Comparison between effect of oral clonidine and tranexamic acid on bleeding during tympanoplasty surgery

Protocol summary

Study aim
Comparison between preoperative clonidine and tranexamic acid on the bleeding during tympanoplasty

Design
In this triple-blind clinical trial study, 62 patients who are candidates for tympanoplasty, referring to Namazi Hospital, will be randomly included in the study. Block randomization will be used to randomly assign people in the study groups. In this method, blocks of 6 (including three people in the intervention group and three people in the comparison group) will be used with a ratio of 1:1.

Settings and conduct
Random Allocation software will be used to generate random sequences. For concealment, the random sequences created in this method are recorded on cards and these cards will be placed in sealed envelopes in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, based on the order of arrival of the eligible participants, the envelopes will be opened and the assigned group of that participant will be known.

Participants/Inclusion and exclusion criteria
Patients aged 18 to 60 years who were candidates for tympanoplasty were included in the study after obtaining informed and written consent. Patients with a history of heart, liver, kidney diseases and severe mental disorders and people treated with tricyclic antidepressants or monoamine oxidase enzyme inhibitors were excluded from the study. patients with high blood pressure those who had systole above 160 mmHg and diastole above 90 mmHg or whose heart rate was less than 50 per minute were excluded from the study.

Intervention groups
90 minutes before the operation, one group was given 200 micrograms of clonidine and the other group was given 250 mg of transgramic acid.

Main outcome variables
Reduce bleeding The satisfaction level of the surgeon during the operation Blood pressure and heart rate control

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230523058274N1**
Registration date: **2023-07-07, 1402/04/16**
Registration timing: **prospective**

Last update: **2023-07-07, 1402/04/16**
Update count: **0**

Registration date
2023-07-07, 1402/04/16

Registrant information

Name
fatemeh izadabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3837 4599

Email address
fatemehizadabadi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between effect of oral clonidine and tranexamic acid on bleeding during tympanoplasty surgery

Public title
Comparison of the effects of clonidine and tranexamic acid on the amount of bleeding during tympanoplasty

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18 to 60 are candidates for tympanoplasty

Exclusion criteria:
Treated with tricyclic antidepressants or monoamine oxidase inhibitors Patients with heart, liver, kidney diseases and severe mental disorders Patients with systolic blood pressure above 160 mmHg and diastolic blood pressure above 90 mmHg. Heart rate less than 50 per minute

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
In this triple-blind clinical trial study, 62 patients who are candidates for tympanoplasty, referring to Namazi Hospital, will be randomly included in the study. Block randomization will be used to randomly assign people in the study groups (intervention group and comparison group). In this method, blocks of 6 (including three people in the intervention group and three people in the comparison group) will be used with a ratio of 1:1. Random Allocation software will be used to generate random sequences. For concealment, the random allocation concealment method will be used in such a way that the random sequences created in this method are recorded on cards and these cards will be placed in sealed envelopes in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, based on the order of arrival of the eligible participants, the envelopes will be opened and the assigned group of that participant will be known.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this three-blind clinical trial study, random allocation concealment method will be used for concealment, in such a way that the random sequences created in this method are recorded on cards and these cards are placed in sealed envelopes. They will be placed in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, based on the order of arrival of the eligible participants, the envelopes will be opened and the assigned group of that participant will be known. The researcher, who is also the outcome assessor, did not know about the grouping, the patients did not know about the grouping and the medicine received, and the data analyzer did not know about the assigned groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Unit 5, 3rd Floor, Mehrdad Building, No. 6, Alley 10, Sanatgar St., Amir Kabir Blvd., Shiraz

City
Shiraz

Province
Fars

Postal code
7176884349

Approval date
2022-04-03, 1401/01/14

Ethics committee reference number
IR.SUMS.MED.REC.1401.435

Health conditions studied

1

Description of health condition studied
Tympanoplasty

ICD-10 code
H60.10

ICD-10 code description
Cellulitis of external ear, unspecified ear

2

Description of health condition studied

Hemorrhage

ICD-10 code

R58

ICD-10 code description

Hemorrhage, not elsewhere classified

Primary outcomes

1

Description

Bleeding

Timepoint

During tympanoplasty surgery

Method of measurement

A 4-point scoring system was evaluated, 0 = no bleeding, 1 = brief (suction rarely), 2 = heavy bleeding (frequent suction) and 3 = very heavy bleeding (conditions of surgical problem and continuous suction).

2

Description

Hemodynamic variables

Timepoint

It was recorded every 10 minutes before and after pre-drug injection, after induction of anesthesia, after intubation, before surgery and then during surgery.

Method of measurement

توسط پرسشنامه

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 90 minutes before the operation, 200 micrograms of clonidine was administered to one group.

Category

Treatment - Drugs

2

Description

Intervention group: 90 minutes before the operation for one group, 200 micrograms of transgrammic acid was given.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Fatemeh Izadabadi

Street address

Department of ENT, Namazi Hospital, Namazi Square, Shiraz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Izadabadi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Research Vice President of Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person
Fatemeh Izadabadi
Position
Resident ent
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Latest degree
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Other areas of specialty/work
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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
Only a part of the data, such as the information related to the main outcome or the like, can be shared.
When the data will become available and for how long
One year after the time of publication
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data will be available only to researchers working in academic and scientific institutions
From where data/document is obtainable
The data will only be available to researchers working in academic and scientific institutions through the following email address. fatemehizadabadi@gmail.com
What processes are involved for a request to access data/document
Only the data related to the main results of the study can be presented to the mentioned people after mentioning the valid reason.
Comments