

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the efficacy and safety of administering of Tranexamic acid and Dexmedetomidine and Nitroglycerine in preventing bleeding and the quality of the surgical site during septorhinoplasty under general anesthesia

Protocol summary

Study aim

Comparison of the efficacy and safety of administering of Tranexamic acid and Dexmedetomidine and Nitroglycerine in preventing bleeding and the quality of the surgical site during septorhinoplasty under general anesthesia

Design

This study is clinical trial and double blind. 105 patients candidate septorhinoplasty surgery in Amirkabir hospital will enter this study. We divide patients in 3 groups by simple randomization. Groups are parallel.

Settings and conduct

105 patients candidate septorhinoplasty surgery in Amirkabir hospital enter this study. This study is double blind. Outcome assessor and analyzer and participant do not know from grouping. Codes of group are available to analyzer and outcome assessor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 60 years, suitable control for blood pressure, no addiction to opioids, body mass index less than 35. Exclusion criteria: Not having satisfaction to perform surgery, sensitivity to the drugs studied, need for prescribing antihypertensive medications, in addition to those used in each group, coagulation disorders, history of cardiovascular disease, pregnancy, chronic pulmonary disease (Asthma)

Intervention groups

First group: 1 micro gram per kilogram Dexmedetomidine during 15 minutes intravenously. Second group: 10 milligram per kilogram Tranexamic acid during 15 minutes intravenously. Third group: 0.5 micro gram per kilogram Nitroglycerine during 15 minutes intravenously.

Main outcome variables

blood pressure; heart rate; oxygen saturation; recovery time; duration of surgery; amount of Propofol consumed;

amount of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N121**

Registration date: **2019-09-24, 1398/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-24, 1398/07/02**

Update count: **0**

Registration date

2019-09-24, 1398/07/02

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 3222 2003

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f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy and safety of administering of Tranexamic acid and Dexmedetomidine and Nitroglycerine in preventing bleeding and the quality of the surgical site during septorhinoplasty under general anesthesia

Public title
Comparison of the efficacy and safety of administering of Tranexamic acid and Dexmedetomidine and Nitroglycerine in preventing bleeding and the quality of the surgical site during septorhinoplasty under general anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
18 to 60 years Suitable control for blood pressure No addiction to opioids Body mass index less than 35
Exclusion criteria:
Not having satisfaction to perform surgery Sensitivity to the drugs studied Need for prescribing low blood pressure drugs, in addition to those used in each group Coagulation disorders History of cardiovascular disease Pregnancy Chronic pulmonary disease(Asthma)

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with randomization with envelopes in three groups A and B and C. In this method, we selected a number of cards or letters as an intervention group 1 and the same number of cards for intervention group 2 and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Researcher who complete

questionnaire and analyzer and participant are blind (double blind). Groups A and B and C are available to analyzer and outcome assessor and participant . The drugs are prepared by the anesthesiologist and will be delivered to the student. That he is not aware of the grouping. The intern evaluates the study's implications.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Arak University Of Medical Sciences
Street address
Vice chancellor for Research, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2019-02-24, 1397/12/05
Ethics committee reference number
IR.ARAKMU.REC.1397.355

Health conditions studied

1

Description of health condition studied
septorhinoplasty
ICD-10 code
J33
ICD-10 code description
Nasal polyp

Primary outcomes

1

Description
Mean arterial blood pressure
Timepoint
Every 15 minutes to end of surgery
Method of measurement
Digital sphygmomanometer

2

Description

Heart rate

Timepoint

Every 15 minutes to end of surgery

Method of measurement

ECG

3

Description

Percent of oxygen saturation

Timepoint

Every 15 minutes to end of surgery

Method of measurement

Pulse oximetry

4

Description

Recovery time

Timepoint

Recovery time

Method of measurement

Chronometer

5

Description

Duration of surgery

Timepoint

End of surgery

Method of measurement

chronometer

6

Description

Amount of Propofol consumed

Timepoint

End of surgery

Method of measurement

Milligram of drug in 24 hours

7

Description

Amount of bleeding

Timepoint

During surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1 micro gram per kilogram

Dexmedetomidine during 15 minutes intravenously.

Category

Treatment - Drugs

2

Description

Intervention group: 10 milligram per kilogram

Tranexamic acid during 15 minutes intravenously.

Category

Treatment - Drugs

3

Description

Intervention group: 0.5 micro gram per kilogram

Nitroglycerine during 15 minutes intravenously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr Hesamodin Modir

Street address

Amirkabir hospital, Parastar square, Arak

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3814957558

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modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Vice chancellor for research, Payambar Azam
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Dr Esmaeel Moshiri

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Shahid Shirodi street, Valiasr square, Valiasr hospital

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Person responsible for updating data

Contact

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Medicine student

Latest degree
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Other areas of specialty/work
General Practitioner

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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
When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Modir Valiasr Hospital, Valiasr square, Shahid Shirodi street 3814957558

What processes are involved for a request to access data/document

Contact With Dr Modir at the following email address.
modir.he@gmail.com

Comments