Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 2026

Comparison of the effect of tranexamic acid and dexmedetomidine on intra-operative bleeding in patients candidate for rhinoplasty

Protocol summary

Summary

Objectives: The aim of this study is to compare the effect of dexmedetomidine and tranexamic acid on intra-operative bleeding within rhinoplasty surgery. Design: Block randomization, double blind, without placebo, single center, trial phase 2, including 76 patients who are candidate for rhinoplasty surgery. Participants including major eligibility criteria: Patients who are candidate for rhinoplasty surgery. Intervention: Tranexamic acid, 10 mg/kg, immediately after anesthesia induction, intravenously. Dexmedetomidine, 1 µg/kg, immediately after anesthesia induction, intravenously. Main outcome measures: Bleeding volume, Surgeon satisfaction, Surgery duration, Recovery duration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122520434N1**
Registration date: **2015-07-16, 1394/04/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-07-16, 1394/04/25

Registrant information

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Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of tranexamic acid and dexmedetomidine on intra-operative bleeding in patients candidate for rhinoplasty

Public title

Comparison of the effect of tranexamic acid and dexmedetomidine on amount of bleeding in cosmetic nose surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patient satisfaction; Age between 18-60 years old; ASA class I-II. Exclusion criteria: Patients with liver, kidney, and cardiovascular diseases or diabetes mellitus; Opium addiction; Using benzodiazepines or clonidine; Sensitivity to study drugs; Pregnancy.

Age

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

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Researcher and patient are not aware of grouping. Blocked randomization is used in this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Headquarters building, 5th floor, intersection of Sheikh Fazl-Allah Noori and Shahid Chamran, Western Hemmat highway, Tehran, Iran
City
Tehran
Postal code
Approval date
2014-08-23, 1393/06/01
Ethics committee reference number
822/105/94ر

Health conditions studied

1

Description of health condition studied
Rhinoplasty
ICD-10 code
Y83.4
ICD-10 code description
Other reconstructive surgery

Primary outcomes

1

Description
Surgeon satisfaction
Timepoint
From the onset of surgery to its end
Method of measurement
Based on surgeon opinion as good, moderate, and bad

2

Description
Bleeding volume
Timepoint
From the onset of surgery to its end
Method of measurement
The number of used gases

3

Description
Blood pressure
Timepoint
From the onset of surgery since 180 minutes later, every 30 minutes
Method of measurement
Sphygmometer

Secondary outcomes

1

Description
Surgery duration
Timepoint
From the onset of surgery to its end
Method of measurement
Minute

Intervention groups

1

Description
Intervention group 1: Tranexamic acid, 10 mg/kg, immediately after anesthesia induction, intravenously.
Category
Prevention

2

Description
Intervention group 2: Dexmedetomidine, 1 µg/kg, immediately after anesthesia induction, intravenously.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool-e Akram hospital
Full name of responsible person
Samira
Street address

Berenjian

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr Seyed Mohsen Ziyaeifard

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Headquarters building, 2nd floor, intersection of Sheikh Fazl-Allah Noori and Shahid Chamran, Western Hemmat highway, Tehran, Iran

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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

Iran University of Medical Sciences, Vice Chancellor for Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Berenjian

Full name of responsible person

Samira

Position

Anesthesiology resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty