

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

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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.

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

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

Name

gita fotoohi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9059

Email address

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
822/105/94

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

City

Tehran

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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Person responsible for updating data

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Name of organization / entity

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Position

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Web page address

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