

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

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

Protocol summary

hassani.v@iums.ac.ir

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

Street address

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

Street address

Headquarters building, 5th floor, intersection of
Sheikh Fazl-Allah Noori and Shahid Chamran, Western
Hemmat highway, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 6435 2326

Fax

Email

S_samira1357@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Samira Berenjian

Position

Anesthesiology resident

Other areas of specialty/work

Street address

Headquarters building, 5th floor, intersection of
Sheikh Fazl-Allah Noori and Shahid Chamran, Western
Hemmat highway, Tehran, Iran

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Phone

+98 21 6435 2326

Fax

Email

S_samira1357@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

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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