

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparative study of the dexmedetomidine and magnesium sulphate in controlled hypotension in patients candidate for rhinoplasty operation

Protocol summary

Summary

Objectives: Comparative study of the dexmedetomidine and magnesium sulphate in controlled hypotension in patients candidate for rhinoplasty operation Study design: 60 patients candidated for rhinoplasty will be recruited and allocated in two groups: dexmedetomidine and magnesium sulphate. The study is unblinded and allocation is by simple randomization. The study is a phase 1/2 trial and single-center. Study method: demographic information and their medical history as well as the following items will be recorded and analyzed: surgical field quality in terms of bleeding and visibility by the surgeon according to the Fromme and colleagues grading method, surgeon's satisfaction score and postsurgical recovery according to the modified Aldrete grading. participants: patients candidate for rhinoplasty surgery in Firouzgar hospital provided informed consent will be included in the current study. Patients with revision rhinoplasty, allergy to one of the drugs in this study, drug abuse and coagulation disorders will be excluded from this study. Interventions: dexmedetomidine and magnesium sulphate as hypotensive agents. Main outcome measures: surgical field quality in terms of bleeding and visibility by the surgeon according to the Fromme and colleagues grading method, surgeon's satisfaction score and postsurgical recovery according to the modified Aldrete grading.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100431487N4**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

مهرداد Mesbah kiaei

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 346 5866

Email address

dr.mmesbah@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Iran University of Medical Sciences

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-22, 1397/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the dexmedetomidine and magnesium sulphate in controlled hypotension in patients candidate for rhinoplasty operation

Public title

Comparison of the effects of two medications in controlled hypotension in patients under rhinoplasty operation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: candidate for rhinoplasty operation; minimum 18 and maximum 50 years of age; ASA grade I; informed consent
Exclusion criteria: revision rhinoplasty; known allergy to drugs being tested; drug abuse; coagulation disorders

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of the Iran University of Medical Sciences

Street address

Next to Milad Tower, Hemmat highway

City

Tehran

Postal code

15459-13487

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.IUMS.REC1395.138340

Health conditions studied

1

Description of health condition studied

Rhinoplasty surgical operation

ICD-10 code

Z41.1

ICD-10 code description

Other plastic surgery for unacceptable cosmetic appearance

Primary outcomes

1

Description

quality of surgical field in terms of bleeding and visibility by surgeon of the operation field

Timepoint

during operation

Method of measurement

Fromme and colleagues 6-point grading system

2

Description

Surgeon's satisfaction score

Timepoint

At the end of the operation

Method of measurement

4-point surgeons satisfaction grading system

3

Description

post-operative recovery rate

Timepoint

After recovery

Method of measurement

Modified Aldrete's Scoring System (duration of the time required to achieve score 9)

Secondary outcomes

empty

Intervention groups

1

Description

Magnesium sulphate (50%) with dose of 40 mg/kg administered in 10 minutes before anesthesia induction and continued with 10-15 mg/kg/hr during the anesthesia.

Category

Treatment - Drugs

2

Description

Dexmedetomidine with bolus dose of 0.1 µg/kg dissolved in 50 milliliters of normal saline and injected 10 minutes before anesthesia induction and continued with infusion of 0.4-0.6 µg/kg/hr during anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar hospital

Full name of responsible person

Dr Soudabeh Djalali

Street address

Behafarin st., Karim Khan Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Kazem Malakouti

Street address

Office of Vice-chancellor for Research, Iran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research, Iran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

Dr Soudabeh Djalali

Position

Faculty member

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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty