Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 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 satisfication 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 satisfication 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

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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
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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