

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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**

**Street address**

Firouzgar hospital, Behafarin st., Karim Khan Ave.

**City**

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1593748711

**Phone**

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soudabehdjalali@yahoo.com

**Web page address**

<http://firoozgar.iums.ac.ir/>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr Soudabeh Djalali

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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*