

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of dexmedetomidine and midazolam to control hemodynamic responses during laryngoscopy and intubation in upper extremity elective surgery

#### Protocol summary

##### Summary

The aim of this study is to compare the effect of midazolam and dexmedetomidine on hemodynamic response control after laryngoscopy and intubation during upper extremity surgery. The study is carried out as a one-center double blind randomized clinical trial on 80 patients in ASA class I and II, being at the age of 18 to 60 years old and candidate for upper extremity elective surgery in Rajai hospital, Qazvin. Patients who are drug abusers or have cardiac and pulmonary diseases and hypertension will be excluded. Randomization will be done through block randomization method. For intervention group, 2 µg/kg fentanyl and 0.6 mg/kg dexmedetomidine and for control group 2 µg/kg fentanyl and 0.05 mg/kg midazolam will be injected as a prodrug. After two minutes, anesthesia induction will be performed using 2 mg/kg propofol and 0.2 mg/kg Atracurium. Three minutes after injection of atracurium, tracheal intubation will be performed through direct laryngoscopy. Systolic and diastolic blood pressure, mean arterial pressure, heart rate and arterial oxygen saturation will be measured at baseline, before of induction, 1, 5, 10, 20, 30, 60 and 90 minutes after intubation, at the end of surgery and at recovery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017040833291N1**

Registration date: **2017-05-04, 1396/02/14**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-05-04, 1396/02/14

#### Registrant information

##### Name

Ali Alizadeh

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3332 0105

##### Email address

a.alizadeh@qums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for research, Qazvin University of Medical Sciences

#### Expected recruitment start date

2017-06-22, 1396/04/01

#### Expected recruitment end date

2018-03-21, 1397/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of dexmedetomidine and midazolam to control hemodynamic responses during laryngoscopy and intubation in upper extremity elective surgery

#### Public title

Comparison of dexmedetomidine and midazolam in hemodynamic response control during tracheal intubation

#### Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: Patients at the age of 18 to 60 years old; class 1 and 2 of America Society of Anesthesiology (ASA); candidate for upper extremity elective surgery; willingness to participate in the study. Exclusion criteria: Difficult intubation; extreme obesity; Cardiac and pulmonary diseases; hypertension; Chronic Diseases; Allergic Diseases; opium addiction; pregnancy; body temperature over 38 degrees Celsius; history of using alpha-2 receptor antagonists; drugs using for high blood pressure (hypertension); Beta blockers; Acute Angle Closure Glaucoma; Lower respiratory tract problems and asthma; hypersensitivity to antihistamine.

### Age

From **18 years** old to **60 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

Patients will be assigned to intervention and control through block randomization method.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of the Qazvin University of Medical Sciences

##### Street address

Shahid Bahonar Blvd, Qazvin

##### City

Qazvin

##### Postal code

3419759811

#### Approval date

2016-10-19, 1395/07/28

#### Ethics committee reference number

IR.QUMS.REC.1395.146

## Health conditions studied

### 1

#### Description of health condition studied

Tracheal intubation

#### ICD-10 code

Y84.8

#### ICD-10 code description

Other medical procedures

## Primary outcomes

### 1

#### Description

Systolic blood pressure

#### Timepoint

at baseline, before of induction, 1, 5, 10, 20, 30, 60 and 90 minutes after intubation, at the end of the surgery and in the recovery room

#### Method of measurement

Monitoring devise

### 2

#### Description

Diastolic blood pressure

#### Timepoint

at baseline, before of induction, 1, 5, 10, 20, 30, 60 and 90 minutes after intubation, at the end of the surgery and in the recovery room

#### Method of measurement

Monitoring devise

### 3

#### Description

Mean arterial blood pressure

#### Timepoint

at baseline, before of induction, 1, 5, 10, 20, 30, 60 and 90 minutes after intubation, at the end of the surgery and in the recovery room

#### Method of measurement

Monitoring devise

### 4

#### Description

Heart rate

#### Timepoint

at baseline, before of induction, 1, 5, 10, 20, 30, 60 and 90 minutes after intubation, at the end of the surgery and in the recovery room

#### Method of measurement

Pulse Oxymetry

### 5

#### Description

Arterial oxygen saturation

#### Timepoint

at baseline, before of induction, 1, 5, 10, 20, 30, 60 and

90 minutes after intubation, at the end of the surgery and in the recovery room

**Method of measurement**

Monitoring devise

**Secondary outcomes**

1

**Description**

Shivering

**Timepoint**

Every 10 min until 30 min after entering the recovery room

**Method of measurement**

Clinical observation

**Intervention groups**

1

**Description**

Intervention group: before induction, 2 µg/kg fentanyl and 0.6 mg/kg dexmedetomidine will be injected as a prodrug.

**Category**

Other

2

**Description**

Control group: before induction, 2 µg/kg fentanyl and 0.05 mg/kg midazolam will be injected as a prodrug.

**Category**

Prevention

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Rajae educational and treatment center

**Full name of responsible person**

Dr. Ali Alizadeh

**Street address**

Rajee Hospital, Padegan Avenu, Qazvin.

**City**

Qazvin

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Amir Peymani

**Street address**

Shahid Bahonar Blvd, Qazvin

**City**

Qazvin

**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 of Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Bijan Heyrat

**Position**

Assistant of Anesthesiology

**Other areas of specialty/work**

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**Name of organization / entity**

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**Full name of responsible person**

Dr. Ali Alizadeh

**Position**

Associate Professor of Anesthesiology

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Ali Alizadeh

**Position**

Assistant Professor of Anesthesiology

**Other areas of specialty/work**

**Street address**

Rajee Hospital, Padegan Avenu, Qazvin

**City**

Qazvin

**Postal code**

**Phone**

## 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*