

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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)

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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 American 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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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