# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Comparison the effects of Dexmedetomidine and Labetalol for induced hypotension in maxillofacial fractures surgery

## Protocol summary

**Study aim**

Comparison the effects of dexmedetomidine and Labetalol for induced hypotension in maxillofacial fractures surgery

**Design**

Patients in the first group receive dexmedetomidine with bolus infusion of 1 µg / kg / h and maintenance dose of 3.0 -5.0 µg/kg/h and in the second group receive infusion of labetalol with bolus dose of 0.3 mg/kg/h and maintenance dose of 0.2-0.5 mg/kg/h .

**Settings and conduct**

The place of study is operation room of Shahid Rajaee Hospital in Qazvin. 0.02 mg/kg of midazolam and 1.5 mg/kg of fentanyl will be used for sedation, 5 mg/kg of lidocaine and 2 mg/kg of propofol will be used for induction of anesthesia and 0.5 mg/kg of atracurium were used as muscle relaxants. Following surgery and stabilization of the patient's hemodynamic status and due to the color of the cards, dexmedetomedine was used in one group and labetalol in the other group. Patient, surgeon, outcome assessor, and statistician were unaware of the type of intervention.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria are age 18 to 60 years, ASA class 1 and 2 and fracture of mandible or maxilla. Exclusion criteria are ASA 3 and more, heart block, heart failure, unstable hemodynamics, depression, renal failure, Raynaud's phenomenon, sensitivity to lidocaine or beta-blockers, deformity of trachea and lack of consent to participate in the study.

**Intervention groups**

In this study, two intervention groups, including the Dexmedetomidine and the Labetalol treatment groups, will be used to induce hypotension in surgery.

**Main outcome variables**

Systolic blood pressure, diastolic blood pressure, mean arterial pressure

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20170408033291N3**
Registration date: **2019-12-30, 1398/10/09**
Registration timing: **retrospective**

Last update: **2019-12-30, 1398/10/09**
Update count: **0**

**Registration date**

2019-12-30, 1398/10/09

**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**

**Expected recruitment start date**

2018-12-22, 1397/10/01

**Expected recruitment end date**

2019-03-20, 1397/12/29

**Actual recruitment start date**

2018-12-22, 1397/10/01

**Actual recruitment end date**

2019-03-20, 1397/12/29

**Trial completion date**

2019-03-20, 1397/12/29

**Scientific title**
Comparison the effects of Dexmedetomidine and Labetalol for induced hypotension in maxillofacial fractures surgery

**Public title**
Comparison the effects of Dexmedetomidine and Labetalol on blood pressure in maxillofacial fractures surgery

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Ages 18 to 60 years Class 1 & 2 of American Anesthesiologists (ASA) Association Classification Fracture of mandible or maxilla

**Exclusion criteria:**
Class 3 or more of American Anesthesiologists (ASA) Association Classification Heart Block Heart Failure Unstable Hemodynamic Depression Renal Failure Raynaud's phenomenon Sensitivity to lidocaine or beta-blockers Deformity of Trachea Lack of consent to participate in the study

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

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **60**
Actual sample size reached: **60**

**Randomization (investigator's opinion)**
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Equal numbers of red and green cards representing the two groups under study are placed in a container and the patient selects a card from the container before entering the operating room. The type of intervention is determined by the color of the card selected. The patient, clinical caregiver, outcome assessor, and statistician were unaware of the study codes.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Qazvin University of Medical Sciences

**Street address**
Bahonar Blvd.

**City**
Qazvin

**Province**
Qazvin

**Postal code**
3419915315

**Approval date**
2018-12-13, 1397/09/22

**Ethics committee reference number**
IR.QUMS.REC.1397.236

## Health conditions studied

### 1

**Description of health condition studied**
Fracture of mandible

**ICD-10 code**
S02.6

**ICD-10 code description**
Fracture of mandible

## Primary outcomes

### 1

**Description**
Systolic blood pressure

**Timepoint**
Before surgery, after intubation, after induction of hypotension, after bolus dose, 3, 5, 10, 15, 30, 60 min after bolus dose, end of operation and recovery.

**Method of measurement**
Using a blood pressure monitor device

### 2

**Description**
Diastolic blood pressure

**Timepoint**
Before surgery, after intubation, after induction of hypotension, after bolus dose, 3, 5, 10, 15, 30, 60 min after bolus dose, end of operation and recovery.

**Method of measurement**
Using a blood pressure monitor device

### 3

**Description**
Mean arterial blood pressure

**Timepoint**
Before surgery, after intubation, after induction of

hypotension, after bolus dose, 3, 5, 10, 15, 30, 60 min after bolus dose, end of operation and recovery.

**Method of measurement**

Using a blood pressure monitor device

## Secondary outcomes

### 1

**Description**

Heart Rate

**Timepoint**

Before surgery, after intubation, after induction of hypotension, after bolus dose, 3, 5, 10, 15, 30, 60 min after bolus dose, end of operation and recovery.

**Method of measurement**

Using cardiac monitoring device

## Intervention groups

### 1

**Description**

First intervention group: Patients in the first group receive dexmedetomidine with bolus infusion of 1µg/kg/h and maintenance dose of 3.0 -5.0 µg/kg/h

**Category**

Treatment - Drugs

### 2

**Description**

Second intervention group: Patients in the second group receive infusion of labetalol with bolus dose of 0.3 mg/kg/h and maintenance dose of 0.2-0.5 mg/kg/h .

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Qazvin Shahid Rajaee Hospital

**Full name of responsible person**

Ali Alizadeh

**Street address**

Bahonar Blvd.

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419915315

**Phone**

+98 28 3333 6001

**Email**

a.alizadeh@qums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Amir Peymani

**Street address**

Bahonar Blvd.

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419915315

**Phone**

+98 28 3333 6001

**Email**

a.alizadeh@qums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Qazvin University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Aydin Binazadeh

**Position**

Resident of Anesthesiology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Bahonar Blvd.

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419915315

**Phone**

+98 28 3333 6001
**Email**
binazadehaydin@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Qazvin University of Medical Sciences
**Full name of responsible person**
Ali Alizadeh
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
Bahonar Blvd.
**City**
Qazvin
**Province**
Qazvin
**Postal code**
3419915315
**Phone**
+98 28 3333 6001
**Email**
a.alizadeh@qums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Qazvin University of Medical Sciences
**Full name of responsible person**
Ali Alizadeh
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
Bahonar Blvd.
**City**
Qazvin
**Province**
Qazvin
**Postal code**
3419915315
**Phone**
+98 28 3333 6001
**Email**
a.alizadeh@qums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
All data is potentially shareable after people are unrecognizable.
**When the data will become available and for how long**
Start of access period from 1399
**To whom data/document is available**
Data will be available only to researchers working in academic and research institutions.
**Under which criteria data/document could be used**
For further research or meta-analysis
**From where data/document is obtainable**
Dr. Ali Alizadeh Email Address: a.alizadeh@qums.ac.ir
**What processes are involved for a request to access data/document**
Permission from Vice-Chancellor for Research and Technology Affairs of Qazvin University of Medical Sciences
**Comments**