

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 Rajaei 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, dexmedetomidine 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)

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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 Rajaei Hospital

Full name of responsible person

Ali Alizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Peymani

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ali Alizadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Specialist

Other areas of specialty/work

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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