

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of Dexmedetomidine and Midazolam on hemodynamic responses after tracheal intubation in elderly patients under Cataract surgery with general anesthesia in comparison to control group in Isfahan Feyz hospital from 2018-2019

Protocol summary

Study aim

The effects of Dexmedetomidine and Midazolam on hemodynamic responses after tracheal intubation in elderly patients under Cataract surgery with general anesthesia in comparison to control group

Design

Randomized double-blinded clinical trial study, Parallel groups with control groups on 195 patients, that randomization was centralized with Random Allocation software

Settings and conduct

The use of two different drugs with specific dose in two intervention groups and use of Normal Saline with the same volume in control group and comparing their effects on hemodynamic responses during tracheal intubation in Cataract surgery in Isfahan Feyz Hospital, that doctor and patient were unaware of the kind of medications

Participants/Inclusion and exclusion criteria

Conclusion criteria: Patients over 65 years old candidate for cataract surgery with general anesthesia with ASA2-3; No allergy to any of the study medications, Exclusion criteria: Hemodynamic changes over 30% that needed intervention; Patient who refusing; Severe drug complications; History of using opioid and alcohol; Changing the method of anesthesia; Severe chronic disease

Intervention groups

First intervention group patients receiving Dexmedetomidine; Second intervention group patients receiving Midazolam; Control group receiving Normal Saline with the same volume

Main outcome variables

Hemodynamic responses

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200510047389N2**

Registration date: **2020-05-19, 1399/02/30**

Registration timing: **retrospective**

Last update: **2020-05-19, 1399/02/30**

Update count: **0**

Registration date

2020-05-19, 1399/02/30

Registrant information

Name

Amir Beidokhti

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

2018-11-22, 1397/09/01

Actual recruitment end date

2019-11-22, 1398/09/01

Trial completion date

Scientific title

The effects of Dexmedetomidine and Midazolam on hemodynamic responses after tracheal intubation in elderly patients under Cataract surgery with general anesthesia in comparison to control group in Isfahan Feyz hospital from 2018-2019

Public title

The effects of Dexmedetomidine and Midazolam on hemodynamic responses after tracheal intubation in elderly patients under Cataract surgery with general anesthesia in comparison to control group

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Elderly patients over 65 years old candidate for cataract surgery with general anesthesia ASA2-3 No allergy to any of the study medications

Exclusion criteria:

Hemodynamic changes over 30% that needed intervention Patient who refusing Severe drug complications History of using opioid and alcohol Changing the method of anesthesia Severe chronic disease

Age

From **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **210**

Actual sample size reached: **195**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided to three groups A, B, C in based on a simple random sampling by Random Allocation

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blinded study the doctor and patient were unaware of type of medications and medications were prepared and encoded by anesthetist

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

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Isfahan University of Medical Sciences., Hezarjarib Street

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Isfahan

Postal code

8174673461

Approval date

2019-03-18, 1397/12/27

Ethics committee reference number

IR.MUI.MED.REC.1397.369

Health conditions studied**1****Description of health condition studied**

Cataract surgery

ICD-10 code

H28

ICD-10 code description

Cataract in diseases classified elsewhere

2**Description of health condition studied**

Tracheal intubation

ICD-10 code

Y84.8

ICD-10 code description

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes**1****Description**

Systolic Blood pressure

Timepoint

Before the anesthesia, 1, 3, 5, 10 during anesthesia, entering the recovery and discharge time

Method of measurement

Blood pressure monitoring device

2**Description**

Diastolic blood pressure

Timepoint

Before the anesthesia, 1, 3, 5, 10 during anesthesia,

entering the recovery and discharge time

Method of measurement

Blood pressure monitoring device

3

Description

Mean arterial Blood pressure

Timepoint

Before the anesthesia, 1, 3, 5, 10 during anesthesia, entering the recovery and discharge time

Method of measurement

Blood pressure monitoring device

4

Description

Heart rate

Timepoint

Before the anesthesia, 1, 3, 5, 10 during anesthesia, entering the recovery and discharge time

Method of measurement

Monitoring device

5

Description

Arterial oxygen saturation percentage

Timepoint

Before the anesthesia, 1, 3, 5, 10 during anesthesia, entering the recovery and discharge time

Method of measurement

Pulse oximetry

Secondary outcomes

1

Description

Surgery complications

Timepoint

After the surgery in recovery

Method of measurement

Physical examination and observation by physician

2

Description

Recovery time

Timepoint

After the surgery

Method of measurement

Minute

Intervention groups

1

Description

Intervention group A: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and vital signs were recorded by

standard monitoring devices including pulse oximeter, capnography, and ECG. Patients in this group received Dexmedetomidine at a dose of 1 mic/kg by slow infusion

Category

Treatment - Drugs

2

Description

Intervention group B: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and vital signs were recorded by standard monitoring devices including pulse oximeter, capnography, and ECG. The second group received Midazolam at a dose of 0.1 mg/kg by slow infusion

Category

Treatment - Drugs

3

Description

Control group: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and vital signs were recorded by standard monitoring devices including pulse oximeter, capnography, and ECG. In this group Normal Saline was given both volume and form with two previous medications.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Feyz Hospital

Full name of responsible person

Khosrou Naghibi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Amir Beidokhti

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to

make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available