Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Dexmedetomidine and Midazolam Anesthesia Effect in Elderly Patients during Cataract Surgery

Protocol summary

Study aim
Comparison of Dexmedetomidine and Midazolam anesthesia effect in elderly patients to be on Cataract surgery.

Design
Clinical trial with parallel group, double blinded, randomized on 121 patients, that Randomization was centralized with Random allocation software

Settings and conduct
The use of two different medications with specific dose and comparing their effects on sedation level and hemodynamic complications in Cataract surgery in Isfahan Feyz Hospital. The patient and doctor were unaware of the kind of medication

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients over 65 years old candidate for Cataract Surgery with ASA2-3; NO allergy to any of 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
Intervention group 1: Elderly patients candidate for Cataract Surgery with Dexmedetomidine Intervention group 2: Elderly patients candidate for Cataract Surgery with Midazolam

Main outcome variables
Anesthesia level; Hemodynamic complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200510047389N1**
Registration date: **2020-05-17, 1399/02/28**
Registration timing: **retrospective**
Last update: **2020-05-17, 1399/02/28**
Update count: **0**

Registration date
2020-05-17, 1399/02/28

Registrant information

Name
Amir Beidokhti

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-14, 1399/02/25

Expected recruitment end date
2020-08-15, 1399/05/25

Actual recruitment start date
2018-09-11, 1397/06/20

Actual recruitment end date
2019-11-11, 1398/08/20

Trial completion date
2019-11-16, 1398/08/25

Scientific title
Comparison of Dexmedetomidine and Midazolam Anesthesia Effect in Elderly Patients during Cataract Surgery

Public title
Comparison of Dexmedetomidine and Midazolam Anesthesia Effect in Elderly Patients during Cataract Surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 65 years old candidate for Cataract Surgery with ASA 2-3 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

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **130**

Actual sample size reached: **121**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided to two groups 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 medication and medication were prepared and encoded by anesthetist

Placebo

Not 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 Science

Street address

Hezarjarib Street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2018-10-03, 1397/07/11

Ethics committee reference number

IR.MUI.MED.REC.1397.042

Health conditions studied

1

Description of health condition studied

Cataract Surgery

ICD-10 code

H28

ICD-10 code description

Cataract in diseases classified elsewhere

Primary outcomes

1

Description

Sedation level

Timepoint

Every 5 minutes during surgery

Method of measurement

Modified Observers Assessment of Alertness/Sedation Scale

Secondary outcomes

1

Description

Systolic Blood pressure

Timepoint

Before the anesthesia, 2, 5, 10, 15 minutes after the start of surgery, Every 15 minute during the surgery, Entering the recovery and 1 hour after the recovery

Method of measurement

Monitoring device

2

Description

Diastolic blood pressure

Timepoint

Before the anesthesia, 2, 5, 10, 15 minutes after the start of surgery, Every 15 minute during the surgery, Entering the recovery and 1 hour after the recovery

Method of measurement

Monitoring device

3

Description

Mean arterial Blood pressure

Timepoint

Before the anesthesia, 2, 5, 10, 15 minutes after the start of surgery, Every 15 minute during the surgery, Entering the recovery and 1 hour after the recovery

Method of measurement

Monitoring device

4

Description
Heart rate
Timepoint
Before the anesthesia, 2, 5, 10, 15 minutes after the start of surgery, Every 15 minute during the surgery, Entering the recovery and 1 hour after the recovery
Method of measurement
Heart rate monitoring device

5

Description
Arterial oxygen saturation percentage
Timepoint
Before the anesthesia, 2, 5, 10, 15 minutes after the start of surgery, Every 15 minute during the surgery, Entering the recovery and 1 hour after the recovery
Method of measurement
Pulse oximetry

6

Description
Pain level
Timepoint
Entering the recovery; Every 15 minute in the recovery
Method of measurement
Visual Analog Scale

7

Description
Surgeon satisfaction
Timepoint
Before the anesthesia, 2, 5, 10, 15 minutes after the start of surgery, Every 15 minute during the surgery, Entering the recovery and 1 hour after the recovery
Method of measurement
Likert questionnaire

8

Description
Patient satisfaction
Timepoint
Before the anesthesia, 2, 5, 10, 15 minutes after the start of surgery, Every 15 minute during the surgery, Entering the recovery and 1 hour after the recovery
Method of measurement
Likert questionnaire

Intervention groups

1

Description
Intervention group: Patients in first group receiving Dexmedetomidine 1 Mic/kg by slow infusion
Category
Treatment - Drugs

2

Description
Intervention group: Patients in second group receiving Midazolam 0.02 mg/kg by slow infusion
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feyz Hospital
Full name of responsible person
Khosrou Naghibi
Street address
Modares Street
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Isfahan
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73461-81764
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh haghjoo javanmard
Street address
Isfahan University of Medical Science., Hezarjarib St
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8174673461
Phone
+98 31 3668 0048
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Sh_haghjoo@med.mui.ac.ir
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
Mahgolsadat Matinkhah
Position
Medical student
Latest degree
Medical doctor
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Person responsible for updating data

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Amir.beidokhti71@gmail.com

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