

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

Isfahan

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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73461-81764

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Naghibi@med.mui.ac.ir

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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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

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Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Medical student

Latest degree

Medical doctor

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Khosrou Naghibi

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Other areas of specialty/work

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Province

Isfahan

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