

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the sedative effect with Dexmedetomidine-Midazolam and Fentanyl- Midazolam in patients who candidated for Phacoemulsification cataract surgery referred to Isfahan Feyz hospital from 2017-2018

Protocol summary

Study aim

Comparison and Determination of the sedative Effect of Fentanyl-dexmedetomidine Combination with Fentanyl-Midazolam during Phacoamulsification

Design

Double blinded clinical trial randomized by Random Allocation and simple random sampling parallel group design of 70 patients enrolled by inclusion and exclusion criteria in this study.

Settings and conduct

The use of two different drugs with specific doses in two groups and comparing their effect on the sedation level in cataract surgery by phacoamulsification in Feyz Hospital in Isfahan. The patient and Researcher unaware of which drugs are used for each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18-85 years old ASA class 1 & 2 scheduled for phacoemulsification cataract surgery and exclusion criteria is refusing, mentally challenged patients, history of chronic use of sedatives, narcotics or alcohol, allergy to any of the study medications, patients with severe chronic obstructive pulmonary disease, Asthma, history of cardiac disease (cardiac block and bradycardia) bradycardia (heart rate less than 50 beats per minute), systolic blood pressure less than 90 mm, Severe hepatic failure, uncontrolled diabetes, left ventricular failure (EF less than 30), and cerebrovascular disease, severe renal failures

Intervention groups

The Intervention group is patient who candidated for phacoamulsification with Fentanyl-dexmedetomidine Combination and Control group is Patient who candidated for Phacoamulsification with Fentanyl-Midazolam combination

Main outcome variables

Sedation level;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N3**

Registration date: **2018-10-15, 1397/07/23**

Registration timing: **retrospective**

Last update: **2018-10-15, 1397/07/23**

Update count: **0**

Registration date

2018-10-15, 1397/07/23

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

hamidshetabi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-11, 1397/03/21

Expected recruitment end date

2018-07-12, 1397/04/21

Actual recruitment start date

2017-06-11, 1396/03/21

Actual recruitment end date

2018-07-12, 1397/04/21

Trial completion date

2018-07-23, 1397/05/01

Scientific title

Comparison of the sedative effect with Dexmedetomidine-Midazolam and Fentanyl- Midazolam in patients who candidated for Phacoemulsification cataract surgery referred to Isfahan Feyz hospital from 2017-2018

Public title

A comparison of sedative effect with dexmedetomidine - fentanyl versus midazolam-fentanyl during cataract surgery with phacoemulsification technique

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients aged 18-85 years old ASA class 1 & 2 scheduled for phacoemulsification cataract surgery

Exclusion criteria:

refusing, mentally challenged patients , history of chronic use of sedatives, narcotics or alcohol , allergy to any of the study medications , patients with severe chronic obstructive pulmonary disease, Asthma,, history of cardiac disease (cardiac block and bradycardia) bradycardia (heart rate less than 50 beats per minute), systolic blood pressure less than 90 mm, Severe hepatic failure, uncontrolled diabetes, left ventricular failure (EF less than 30), and cerebrovascular disease,severe renal failures

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **70**

Actual sample size reached: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

The division of patients into two groups is based on a simple random sampling and Random allocation

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double blinded. Patient and researcher are unaware of patient groups and type of medication. The medications are prepared by an anesthetist and encoded and then injected. Demographic information; Sedation level. The quality of pain relief and hemodynamic variables and complications are collected by a patient who is not aware of the type of drug and patient grouping.

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 Sciences

Street address

Isfahan University of medical sciences, Hezar Jarib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR.MUI.MED.REC.1397.051

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

Ramsay sedation score

Secondary outcomes

1

Description

Medium atrial Blood pressure

Timepoint

Immediately before surgery, every 5 minutes during surgery and every 10 minutes for 30 minutes in recovery

Method of measurement

Pressure gauge

2

Description

Oxygen saturation percentage

Timepoint

Immediately before surgery, every 5 minutes during and after surgery every 10 minutes for 30 minutes in recovery

Method of measurement

Pulse oximetry

3

Description

Heart rate

Timepoint

Immediately before surgery, every 5 minutes during and after surgery every 10 minutes for 30 minutes in recovery

Method of measurement

Pulse oximetry

4

Description

Surgeon satisfaction

Timepoint

Immediately before surgery, every 5 minutes during and after surgery every 10 minutes for 30 minutes in recovery

Method of measurement

Likert questionnaire

5

Description

Patient satisfaction

Timepoint

Immediately before surgery, every 5 minutes during and after surgery every 10 minutes for 30 minutes in recovery

Method of measurement

Likert questionnaire

6

Description

adverse drug reactions

Timepoint

Immediately before surgery, every 5 minutes during and after surgery every 10 minutes for 30 minutes in recovery

Method of measurement

Adverse drug reaction questionnaire

7

Description

Pain intensity

Timepoint

Immediately before surgery, every 5 minutes during and after surgery every 10 minutes for 30 minutes in recovery

Method of measurement

Universal Pain assessment tool

8

Description

Recovery time

Timepoint

After completing the intervention until the withdrawal from the recovery

Method of measurement

Minutes

Intervention groups

1

Description

Intervention group:patient in group (FD) received 1µg/kg Fentanyl with 0/5 µg/kg Dexmedetomidine in 20cc Normal salin for 10 minutes and then the continuous infusion of Dexmedetomidine 0/5 µg/kg/hr until the end of surgery.

Category

Treatment - Drugs

2

Description

Control group:patient in group (FM) received 1µg/kg Fentanyl with 0/05 mg/kg Midazolam in 20cc Normal salin for 10 minutes and then the continuous infusion of Midazolam 0/05 mg/kg/hr until the end of surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz Hospital

Full name of responsible person

Hamidreza Shetabi

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Feyz Hospital , Modares St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh haghjooy javanmard

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Vice chancellor of research and technology of university, Isfahan University of Medical Sciences, Hezarjarib St.

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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

Hamidreza Shetabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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