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 Randome 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 Fentayl-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

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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 midazolaml–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 an 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
Isfehan

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
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Person responsible for updating data

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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