

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparative investigation of Dexmedetomidine Hemodynamic infusion by intermittent injection of sufentanil-midazolam on sedation of patients during cataract surgery

Protocol summary

Summary

This study will be done to compare Dexmedetomidine Hemodynamic infusion and intermittent injection of sufentanil-midazolam on sedation of patients during cataract surgery. This study is a double blind clinical trial. The study population will include all patients scheduled for cataract surgery referred to Imam Khomeini hospital, Kermanshah city. 60 eligible patients will be selected by available sampling method and randomly divided into two D and S groups. In the experimental group D, from 10 min before the beginning of operation Dexmedetomidine at the dose of 0.5 µg / kg will be infused by anesthesiology assistant and in the experimental group S, sufentanil 0.1 µg / kg and midazolam 0.2 µg / kg will be injected 5 minutes before the start of operation and Dexmedetomidine infusion at a dose of 0.02 µg / kg / h will be continued. MAP- HR- SP2 will be recorded before infusion and every 5 min after infusion by anesthesia assistant and the level of sedation and relief based on Ramsey standards will be measured and compared in both groups. Inclusion criteria: Age between 30 -70 years; ASA class I, II, III. Exclusion criteria: Pregnant women; Patients with lung disease; Kidney disease; Liver disease; Blood pressure greater than 180; Blood pressure less than 90; Heart rate greater than 120; Heart rate less than 60; History of Alcohol or drugs use, chronic use of analgesics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061014333N77**
Registration date: **2017-07-18, 1396/04/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-18, 1396/04/27

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

froughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-06-20, 1396/03/30

Expected recruitment end date

2017-08-21, 1396/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigation of Dexmedetomidine Hemodynamic infusion by intermittent injection of sufentanil-midazolam on sedation of patients during cataract surgery

Public title

Investigation of Dexmedetomidine Hemodynamic infusion on sedation during cataract surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 30 -70 years; ASA class I, II, III. Exclusion criteria: Pregnant women; Patients with lung disease; Kidney disease; Liver disease; Blood pressure greater than 180; Blood pressure less than 90; Heart rate greater than 120; Heart rate less than 60; History of Alcohol or drugs use, chronic use of analgesics

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Based on random numbers table. In this way, a code is assigned to the sample. The researcher to select a sample from the table, start by chance from a point of table to the row or column.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Postal code

Approval date

2017-05-03, 1396/02/13

Ethics committee reference number

kums.rec.1396.35

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H25

ICD-10 code description

Senile Cataract

Primary outcomes

1

Description

Sedation

Timepoint

After the end of the study

Method of measurement

Based on Ramsey Hunt standard

Secondary outcomes

empty

Intervention groups

1

Description

In the experimental group D, 0.5µg /kg Dexmedetomidine will be injected by anesthesiology assistant from 10 min before the beginning of operation.

Category

Treatment - Drugs

2

Description

In the experimental group S, 0.1µg /kg Sufentanil and 0.2 µg/kg Midazolam will be injected by anesthesiology assistant from 10 min before the beginning of operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Azam Tavakolifar

Street address

Imam Khomeini Hospital, Naghliyah Street

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, ShahidBeheshti Boulevard

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

kermanshah University of Medical Sciences

Full name of responsible person

Azam Tavakolifar

Position

Residents of anesthesiology

Other areas of specialty/work**Street address**

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Postal code**Phone**

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Person responsible for scientific

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Contact**Name of organization / entity**

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Full name of responsible person

Dr. Naser Yeganeh

Position

Anesthesiologist

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Person responsible for updating data

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Full name of responsible person

Azam Tavakolifar

Position

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty