

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative study of changes in heart rate and blood pressure in the use of Dosecam Ketamine with Dexmedetomidine and Dosecam Ketamine with Propofol in cataract surgery under local anesthesia by phacoemulsification method.

Protocol summary

Study aim

Investigating the effect of changes in heart rate and blood pressure in the use of Dosecam Ketamine with Dexmedetomidine and Dosecam Ketamine with Propofol in cataract surgery by phacoemulsification method

Design

A randomized, controlled, double-blind, placebo-controlled clinical trial with a sample size of 128 patients was designed in a phase 3 trial.

Settings and conduct

This is a randomized double-blind clinical trial that will be conducted on 60 patients who are candidates for cataract surgery in Faiz Hospital, Isfahan. After the approval of the ethics committee of the university and obtaining the consent of the patients, the patients are randomly allocated into groups, in each group the desired intervention is applied and the patient's clinical symptoms are recorded. The person who applies the intervention is different from the researcher who evaluates the symptoms and also They do not know the type of intervention. Even though the patients are included in the study, they are not aware of the type of intervention applied and therefore they are all blind.

Participants/Inclusion and exclusion criteria

Patients aged 18 years and above r who undergo cataract surgery for the first time by phacoemulsification method and are in ASA class 1 to 3. Non-entry criteria: Patients with obstructive sleep apnea, diabetes, mental illnesses, autoimmune diseases, nystagmus, leukemia, epilepsy, patients treated with psychiatric drugs, deafness and drug allergy and use of painkillers in the past week, BMI index greater than 35 .

Intervention groups

People who take the first combination of ketamine with dexmedetomidine in group a and people who take the second combination of medicine with dexmedetomidine

and group b are placed in the group of the second combination of medicine and ketamine with propofol.

Main outcome variables

Heart rate ;blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N43**

Registration date: **2022-09-07, 1401/06/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-07, 1401/06/16**

Update count: **0**

Registration date

2022-09-07, 1401/06/16

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of changes in heart rate and blood pressure in the use of Dosecam Ketamine with Dexmedetomidine and Dosecam Ketamine with Propofol in cataract surgery under local anesthesia by phacoemulsification method.

Public title

Comparative study of changes in heart rate and blood pressure in the use of Dosecam Ketamine with Dexmedetomidine and Dosecam Ketamine with Propofol in cataract surgery under local anesthesia by phacoemulsification method.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients 18 years and older For the first time, they undergo cataract surgery using phacoemulsification be in ASA class 1 to 3

Exclusion criteria:

Patients with obstructive sleep apnea diabetes , mental illnesses , Autoimmune diseases Nystagmus Leukemia , epilepsy Patients treated with psychiatric drugs , Deafness Drug allergy Use of painkillers in the past week BMI index greater than 35

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are collected by easy and continuous sampling method. . Then the samples were randomly divided into two groups by computer randomization using relevant software. Sampling continues until the samples reach the set limit. Sampling is done using unique codes and they are placed in 2 groups a or b. People who take the first combination of ketamine with dexmedetomidine in group a and people who take the second combination of medicine with dexmedetomidine and group b are placed in the group of the second combination of medicine and ketamine with propofol.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The method of blinding is that patients are unaware of the type of drug they are given and drugs provided in similar syringes and coded for those by the researcher and given to the study expert to inject. and the hemodynamic changes are monitored and recorded, so the attending, the clinical caregiver, the examiner, and the data analyzer will not understand the type of medication and the investigator deciphers the codes after data analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences

Street address

Hezar Jarib

City

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8174673461

Approval date

2022-05-08, 1401/02/18

Ethics committee reference number

IR.MUI.MED.REC.1401.047

Health conditions studied**1****Description of health condition studied**

heart rate

ICD-10 code

R00.1

ICD-10 code description

Bradycardia, unspecified

2**Description of health condition studied**

Hypotension

ICD-10 code

I95

ICD-10 code description

Hypotension

Primary outcomes

1

Description

heart rate

Timepoint

Before injecting anesthetic, one minute after injecting anesthetic, five minutes after injecting anesthetic, every ten minutes during surgery and every ten minutes during recovery until discharge.

Method of measurement

NIBP Noninvasive Blood Pressure measurement by an anesthesiologist

2

Description

bloodpressure

Timepoint

Before injecting anesthetic, one minute after injecting anesthetic, five minutes after injecting anesthetic, every ten minutes during surgery and every ten minutes during recovery until discharge.

Method of measurement

NIBP Noninvasive Blood Pressure measurement by an anesthesiologist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: First, informed consent is obtained from the patients. After placing the patients on the bed of the operating room, standard monitoring including blood pressure gauges and basic vital signs are recorded. Ketamine is injected intravenously with dexmedetomidine to the patient, the desired variables are recorded at the desired times.

Category

Treatment - Drugs

2

Description

Intervention group: First, informed consent is obtained from the patients. After placing the patients on the bed of the operating room, standard monitoring including blood pressure gauges and basic vital signs are recorded. Ketamine is injected intravenously with dexmedetomidine to the patient, the desired variables are recorded at the desired times.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faiz Hospital

Full name of responsible person

Behzad Nazemroaya

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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
Behzad Nazemroaya
Position
Associate Professor
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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