Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effectiveness of two compounds Propofol - Sodium thiopental and Propofol - Etomidate on the quality of sedation and hemodynamic changes in Cataract surgery

Protocol summary

Study aim

The effect of Propofol-Thiopental and Propofol-Etomidate combination on sedation and hemodynamic status of the patient in cataract surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 64 patients. Lottery and sealed envelopes are used for randomization.

Settings and conduct

This is a randomized double-blind clinical trial that will be performed on 64 patients undergoing cataract surgery at Feyz Hospital in Isfahan; After the approval of the university ethics committee and obtaining the patients' consent, the patients entered the groups by random allocation. In each group, the desired intervention is applied and the patient's clinical symptoms are recorded. They do not know the type of intervention. Patients, despite being studied, are not aware of the type of intervention and are therefore all blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 to 60 years old, Candidate for Cataract Surgery, Class I and II ASA Anesthesia
Exclusion criteria: heart disease, mental illness, obesity, diabetes, drug allergies and addiction

Intervention groups

Intervention group A: In this group, patients receive 1 mg per kg of body weight of Propofol-Thiopental sodium for anesthesia. Intervention group B: In this group, patients receive 0.3 mg per kg of body weight of Propofol-Etomidate for anesthesia.

Main outcome variables

The amount of patient sedation during the operation; The rate of hemodynamic changes in the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N37**
Registration date: **2021-10-16, 1400/07/24**
Registration timing: **prospective**

Last update: **2021-10-16, 1400/07/24**
Update count: **0**

Registration date

2021-10-16, 1400/07/24

Registrant information

Name
Behzad Nazemroaya
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 31 3212 3543
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behzad_nazem@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of two compounds Propofol - Sodium thiopental and Propofol - Etomidate on the quality of sedation and hemodynamic changes in Cataract surgery

Public title
Effectiveness of two compounds Propofol - Sodium thiopental and Propofol - Etomidate in Cataract surgery

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Patients 18 to 60 years Grade I, II and III in ASA criteria (American Society of Anesthesia) Candidate for Cataract surgery

Exclusion criteria:
Patients with obstructive sleep apnea, mental disorder, autoimmune diseases, diabetes, nystagmus, leukemia, epilepsy and patients treated with psychiatric drugs Deafness Allergy to the drugs used Use of painkillers in the past week BMI (Body Mass Index) more than 35

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
This is a simple randomized clinical trial in which individuals enter study groups by lottery; The drugs are placed in the desired number in sealed opaque and uniformly sealed bags. Each of the codes is also written on a piece of paper, folded and placed inside a box. After entering the operating room, each patient takes one of the papers out of the box. Which is applied to the patient. This continues until the end of the paperwork so that the number of patients in the desired volume in the groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blind clinical trial; In this way, before obtaining consent, patients are studied but do not know which group they will be in and therefore are blind. Also, the nurse who injects the drug and the researcher who records the patient's symptoms do not know the type of drug and are blind.

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 St

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-06-22, 1400/04/01

Ethics committee reference number
IR.MUI.MED.REC.1399.650

Health conditions studied

1

Description of health condition studied
Cataract

ICD-10 code
H25

ICD-10 code description
Age-related cataract

Primary outcomes

1

Description
Heart Rate

Timepoint
Before drug injection, 1 and 5 minutes after drug injection and then every 10 minutes until the end of recovery

Method of measurement
ECG monitoring

2

Description
Sadation quality

Timepoint
Before drug injection, 1 and 5 minutes after drug injection and then every 10 minutes until the end of recovery

Method of measurement
RSS criteria (Ramsey sedation score)

3

Description
mean arterial blood pressure
Timepoint
Before drug injection, 1 and 5 minutes after drug injection and then every 10 minutes until the end of recovery
Method of measurement
Barometer

4

Description
Arterial blood oxygen saturation
Timepoint
Before drug injection, 1 and 5 minutes after drug injection and then every 10 minutes until the end of recovery
Method of measurement
Pulse oximeter

Secondary outcomes

1

Description
Rate of nausea and vomiting
Timepoint
Before drug injection, 1 and 5 minutes after drug injection and then every 10 minutes until the end of recovery
Method of measurement
Observation and asking

2

Description
Duration of anesthesia
Timepoint
From the time the first sedation drug is administered until the effects of anesthesia are over
Method of measurement
o'clock

3

Description
Duration of surgery
Timepoint
From the time the surgeon starts the cataract until the lens is done
Method of measurement
o'clock

Intervention groups

1

Description
Intervention group A: In this group, eligible patients, after being placed on a surgical bed and monitoring connection, first receive 300 ml per hour of normal saline for preoperative fluid therapy, then they are given 1 mg per kg body weight of Propofol. (Diateb Company) - Sodium thiopental (Jaber Ibn Hayyan Company) is injected to induce anesthesia. The patient's clinical signs and hemodynamic changes are idolized at regular intervals until the end of recovery.
Category
Treatment - Drugs

2

Description
Intervention group B: In this group, eligible patients, after being placed on a surgical bed and monitoring connection, first receive 300 ml per hour of normal saline for preoperative fluid therapy, then they are given 0.3 mg per kg body weight of Propofol. (Diateb Company) - Sodium thiopental (Jaber Ibn Hayyan Company) is injected to induce anesthesia. The patient's clinical signs and hemodynamic changes are idolized at regular intervals until the end of recovery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feyz hospital
Full name of responsible person
Behzad Nazemoroaya
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ali Aria
Position
Medical student
Latest degree
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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