

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison Of Anesthesia With Sevoflurane Versus Propofol On The Extubation Time And Recovery Parameters In The Patients Undergoing Cataract Surgery In Shahid Mohammadi Hospital

Protocol summary

Study aim

Comparison Between Sevoflurane And Propofol on Extubation Time And Recovery Parameters In Cataract Surgery

Design

Randomized three-blind clinical Trial with parallel groups designed with 60 patients from 23-05-2020 to 24-08-2020.

Settings and conduct

This Study will perform in shahid Mohammadi Hospital in Bandar-e Abas. The patient enters the study with written consent and doesn't know which group she/he will be study. The person who evaluates the patient in recovery does not know how the patient is anesthetized group. (case or control)

Participants/Inclusion and exclusion criteria

Inclusion criteria: The Patients with 18- 75 Years Old Candidates for Cataract Surger ASA 1- 2 Exclusion Criteria: ASA 3- Urgent surgery- Co- Existing Surgery With Cataract eg, Glucoma- Hepatic Failure- Renal Failure- Drug Sensitivity- Obesity (BMI>30)

Intervention groups

This prospective clinical trial study will be performed on 60 patients 18-75 years old with ASA 1 and 2 who candidate for cataract surgery. Patients will randomly divided to two groups (30 patients each group). In the first group anesthesia will maintain with propofol 100 µg / kg / min and in the second group, sevoflurane(0. 5- 1.5%). Demographic data, hemodynamic parameters, surgical characteristics, pain severity and patient satisfaction will record. Data will analyzed by statistical tests and P <0.05 will be considered significant.

Main outcome variables

Extubation Time- Awakening Time- Nausea and Vomiting- Postoperative Pain- Postoperative Blood Pressure- Heart Rate- Discharge time from Recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200425047194N1**

Registration date: **2020-11-11, 1399/08/21**

Registration timing: **retrospective**

Last update: **2020-11-11, 1399/08/21**

Update count: **0**

Registration date

2020-11-11, 1399/08/21

Registrant information

Name

Abdorasoul Anvaripour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 77 3333 1925

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-23, 1399/03/03

Expected recruitment end date

2020-08-24, 1399/06/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Of Anesthesia With Sevoflurane Versus Propofol On The Extubation Time And Recovery Parameters In The Patients Undergoing Cataract Surgery In Shahid Mohammadi Hospital

Public title

Comparison Between Propofol And Sevoflurane on Recovery From Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidates for Cataract Surgery No History of Systemic Disease Controlled with a History of Systemic Disease

Exclusion criteria:

Obesity With BMI More Than 30 Urgent Surgery Uncontrolled Systemic disease With Complication Renal Failure Hepatic Failure Complex Eye Surgery With Cataract Surgery eg. Glucoma Drug Sensitivity

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients to whom the inclusion criteria apply are randomly divided into two groups using the table obtained by Random Allocation Software. This software creates a random sequence by blocking. Each patient participating in the study will receive a unique code and the person performing the randomization with the software will not be aware of the next steps and interventions. After assigning the code, patients will be divided into two groups. Then, to maintain anesthesia, the first group is given Propofol and the second group is given Sevoflurane.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient enters the study with written consent and doesn't know which group she/he will be study. The person who evaluates the patient in recovery does not know how the patient is anesthetized group. (case or control)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hormozgan University of Medical Sciences Ethics Commity

Street address

Anesthesiology Department, Shahid Mohammadi Hospital, Jomhourye Eslami Blv,

City

Bandar-e Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2017-05-15, 1396/02/25

Ethics committee reference number

HUMS.REC.1396.009

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

Extubation time

Timepoint

End of surgery

Method of measurement

From the End of Surgery to Patient Extubation

2

Description

Patient Awakening

Timepoint

From the hold of Anesthetic Drugs to Patient Verbal stimulation Response

Method of measurement

Eye Opening

3

Description

Nausea and Vomiting

Timepoint

Recovery Room

Method of measurement

Marshal Criteria

4**Description**

Post Operative Pain

Timepoint

Recovery Room

Method of measurement

Visual analogue Scale

5**Description**

Postoperative Blood Pressure

Timepoint

Recovery Room

Method of measurement

Non Invasive blood Pressure

6**Description**

Sedative Status

Timepoint

Recovery Room

Method of measurement

Ramsay Scale

7**Description**

Heart Rate

Timepoint

Recovery Room

Method of measurement

Monitoring

8**Description**

Saturation of Peripheral Oxygenation

Timepoint

Recovery Room

Method of measurement

Monitoring

9**Description**

Discharge Time From Recovery

Timepoint

Recovery Room

Method of measurement

Marshal Criteria

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: In patients in the first group, Propofol at a concentration of 10 mg/cc is used as an intravenous infusion of 100µg/kg/min to maintain anesthesia.

Category

Treatment - Drugs

2**Description**

Intervention group 2: In the second group of patients, Sevoflurane is used in the amount of 0.5-1.5% by inhalation to maintain anesthesia.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Mohammadi Hospital

Full name of responsible person

Hashem Jarineshin

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bandare-abbas 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

Bandare-abbas 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**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Hashem Jarineshin

Position

Associate 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