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 Rrecovery 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 1and 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
Street address
Jomhurye Eslami Blv
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Agha Mollaei
Street address
Jomhurye Eslami Blv, Shahid Mohammadi Hospital
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Email
hjarineshin@yahoo.com
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