Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The comparative analysis of post-operative delirium incidence: sevoflurane vs propofol in geriatric patients under general anaesthesia

Protocol summary

Study aim

To compare the incidence of postoperative delirium in elderly patients receiving propofol-based versus sevoflurane-based general anesthesia

Design

A randomised, parallel group, superiority clinical trial comparing propofol-based versus sevoflurane-based anesthesia in elderly surgical patients, with concealed allocation and blinded outcome assessment using the Confusion Assessment Method over seven postoperative days.The study enrolled 200 patients, with 100 patients in each group.

Settings and conduct

The study was conducted at the Department of Anesthesia, Allied Hospital, Faisalabad over 6 months. After ethical approval and informed consent, patients aged 60–90 years undergoing elective moderate-risk surgery under general anesthesia were randomly assigned to receive either propofol- or sevoflurane-based anesthesia. Postoperative delirium was assessed twice daily for 7 days using the CAM by trained, blinded assessors.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients of both genders having age 60-90 years .Patients undergoing for elective surgery under general anesthesia American society of Anesthesiology I-III Exclusion criteria: Patients with Preoperative delirium, History of dementia ,Psychiatric disease like schizophrenia, epilepsy, Parkinson's disease or myasthenia gravis ,Hepatic or renal dysfunction ,Requirement for postoperative mechanical ventilation ,History of surgery within the recent six months ,Allergy to any of the study drugs

Intervention groups

Group A patients will receive sevoflurane based anesthesia while Group-B patients will receive propofol based anesthesia

Main outcome variables

The primary outcome variable is the incidence of postoperative delirium within 7 days after surgery, assessed using the Confusion Assessment Method. Delirium is recorded as a binary outcome (Yes/No) based on CAM diagnostic criteria during twice-daily evaluations

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250524065864N1**
Registration date: **2025-05-27, 1404/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-27, 1404/03/06**
Update count: **0**

Registration date

2025-05-27, 1404/03/06

Registrant information

Name

Muhammad Khalid

Name of organization / entity

Faisalabad Medical University & Affiliated Hospitals

Country

Pakistan

Phone

+92 41 8520652

Email address

irslan3310@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-05, 1403/09/15

Expected recruitment end date

2025-06-05, 1404/03/15

Actual recruitment start date

2024-12-05, 1403/09/15

Actual recruitment end date

2025-06-06, 1404/03/16

Trial completion date

2025-06-10, 1404/03/20

Scientific title

The comparative analysis of post-operative delirium incidence: sevoflurane vs propofol in geriatric patients under general anaesthesia

Public title

Comparing the risk of post-surgery delirium in older adults: sevoflurane vs propofol anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both gender 60-90 Patients undergoing for Mild to moderate risk elective surgery American society of Anesthesiology (ASA) I-III

Exclusion criteria:

Patient with preoperative delirium History of dementia Psychiatric disease like schizophrenia, epilepsy, Parkinson's disease or myasthenia gravis Hepatic or renal dysfunction Requirement for postoperative mechanical ventilation Allergy to any of the study drugs History of surgery within the recent six months

Age

From **60 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **200**

More than 1 sample in each individual

Number of samples in each individual: **100**

Each individual participant in the study contributes a comprehensive set of clinical observations and measurements. This includes demographic data such as age, gender, body mass index (BMI), residential address, and contact information. Medical history is recorded, encompassing ASA physical status classification (I–III), the presence of comorbid conditions like hypertension, diabetes, and cardiovascular disease, as well as smoking status. Surgical details are documented, specifying the type of surgery performed and the anesthetic agent administered—either sevoflurane or propofol. The primary clinical outcome, postoperative delirium, is assessed using the Confusion Assessment Method (CAM), conducted twice daily for up to seven days following surgery. Each CAM evaluation captures specific features including attention deficits, disorganized thinking, altered level of consciousness, and other neurocognitive disturbances. The main outcome variable is the presence or absence of postoperative delirium (Yes/No) as determined by the CAM criteria.

Actual sample size reached: **200**

More than 1 sample in each individual

Actual sample size in each individual: **100**

Each individual participant in the study contributes a comprehensive set of clinical observations and measurements. This includes demographic data such as age, gender, body mass index (BMI), residential address, and contact information. Medical history is recorded, encompassing ASA physical status classification (I–III), the presence of comorbid conditions like hypertension, diabetes, and cardiovascular disease, as well as smoking status. Surgical details are documented, specifying the type of surgery performed and the anesthetic agent administered—either sevoflurane or propofol. The primary clinical outcome, postoperative delirium, is assessed using the Confusion Assessment Method (CAM), conducted twice daily for up to seven days following surgery. Each CAM evaluation captures specific features including attention deficits, disorganized thinking, altered level of consciousness, and other neurocognitive disturbances. The main outcome variable is the presence or absence of postoperative delirium (Yes/No) as determined by the CAM criteria.

Randomization (investigator's opinion)

Randomized

Randomization description

This study was designed as a randomized controlled trial (RCT) to compare the incidence of post-operative delirium (POD) in geriatric patients undergoing surgery under general anesthesia with either propofol or sevoflurane. Eligible participants were randomly assigned to one of two groups: Group A received propofol-based general anesthesia, while Group B received sevoflurane-based general anesthesia. Randomization was performed using a computer-generated sequence to ensure equal and unbiased allocation, with allocation concealment maintained to minimize selection bias. Post-operatively, all patients were closely monitored for signs of delirium using a validated assessment tool, such as the Confusion Assessment Method (CAM). The primary outcome measured was the incidence of POD within 72 hours after surgery. This randomized design enabled a direct and unbiased comparison of the effects of propofol and sevoflurane on the development of post-operative delirium in older surgical patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study was designed as a single-blinded randomized controlled trial (RCT) to compare the incidence of post-operative delirium (POD) in geriatric patients undergoing surgery under general anesthesia with either propofol or sevoflurane. Eligible participants were randomly assigned to one of two groups: Group A received propofol-based general anesthesia, while Group B received sevoflurane-based general anesthesia. Randomization was performed using a computer-generated sequence to ensure equal and unbiased allocation, with allocation concealment maintained to minimize selection bias. In this single-blinded design, patients were unaware of the type of anesthesia they received, while the anesthesia providers were informed

due to the nature of drug administration. Post-operatively, all patients were closely monitored for signs of delirium using a validated assessment tool, such as the Confusion Assessment Method (CAM). The primary outcome measured was the incidence of POD within 72 hours after surgery. This randomized and blinded design allowed for a more objective and unbiased comparison of the effects of propofol and sevoflurane on the development of post-operative delirium in older surgical patients.

Placebo

Not used

Assignment

Parallel

Other design features

Length of hospital stay, Severity and duration of Post Op delirium

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Secretariat Ethical Review Committee National Institute of Heatth, Research Centre

Street address

Ground Floor Anatomy Department Faisalabad medical university Faisalabad

City

Faisalabad

Postal code

38000

Approval date

2024-12-05, 1403/09/15

Ethics committee reference number

48.ERC/FMU/2023-24/546

Health conditions studied

1

Description of health condition studied

Post-operative delirium (POD) is a common and serious complication that occurs after surgery, particularly in older adults. It is characterized by an acute and fluctuating disturbance in attention, awareness, and cognition, typically arising within the first few days following anesthesia and surgery. POD can manifest as confusion, disorientation, memory disturbances, hallucinations, or agitation, and may vary in intensity and duration. It is associated with increased morbidity, prolonged hospital stays, higher healthcare costs, and a greater risk of long-term cognitive decline or institutionalization. Various factors contribute to the development of POD, including advanced age, pre-existing cognitive impairment, type of surgery, and the choice of anesthetic agents. Early detection and appropriate management are essential to improving patient outcomes and minimizing the impact of this condition.

ICD-10 code

F05.8

ICD-10 code description

Post-operative delirium (POD) is a common and serious complication that occurs after surgery, particularly in older adults. It is characterized by an acute and fluctuating disturbance in attention, awareness, and cognition, typically arising within the fi

Primary outcomes

1

Description

Post Operative Delirium

Timepoint

During the first seven post-operative days, delirium will be assessed twice each day, that is, between 8–10 am and 6–8 pm, by using CAM. Delirium will be assessed as per operational definition. All the information will be recorded on performa by myself

Method of measurement

Confusion Assessment Method

Secondary outcomes

1

Description

Reduce hospital stay and better outcomes

Timepoint

During the first seven post-operative days, delirium will be assessed twice each day, that is, between 8–10 am and 6–8 pm, by using CAM

Method of measurement

Confusion Assessment Method (CAM)

Intervention groups

1

Description

Intervention group: Group A received sevoflurane-based anesthesia, while Group B received propofol-based anesthesia. All participants were induced with intravenous propofol (1–2 mg/kg), nalbuphine (0.1–0.2 mg/kg), and atracurium (0.5 mg/kg).Anesthesia in Group A was maintained using inhaled sevoflurane, titrated to achieve a BIS value between 40 and 60.

Category

Treatment - Drugs

2

Description

Intervention group: Group B received target-controlled infusion (TCI) of propofol to maintain a BIS value within the same range. Muscle relaxation in both groups was maintained with continuous atracurium infusion (10

µg/kg/min)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Allied Hospital Faisalabad

Full name of responsible person
DrMuhammad Irsalan Khalid

Street address
Masjid Ismail Rd, Faisalabad

City
Faisalabad

Postal code
38000

Phone
+92 41 8520652

Email
irslan3310@gmail.com

Web page address
https://ahfsd.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Faisalabad medical university

Full name of responsible person
Professor Dr Zafar Ali Choudry

Street address
Masjid Ismail Rd, Faisalabad

City
Faisalabad

Postal code
38000

Phone
+92 343 7693310

Email
irslan3310@gmail.com

Web page address
https://ahfsd.pk/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Faisalabad medical university

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
Allied Hospital faisalabad

Full name of responsible person
Dr Humaira Ahmad

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Masjid Ismail Rd, Faisalabad

City
Faisalabad

Province
Punjab

Postal code
38000

Phone
+92 333 5824895

Email
Humaira_ahmad21@hotmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Allied Hospital Faisalabad

Full name of responsible person
Dr Ammara Liaqat

Position
Consultant

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
Masjid Ismail Rd, Faisalabad

City
Faisalabad

Province
Punjab

Postal code
38000

Phone
+92 332 1752600

Email
Ammaraliaqat22@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Allied Hospital Faisalabad

Full name of responsible person
Dr Sehar Shafiq
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Masjid Ismail Rd, Faisalabad
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
+92 343 7693310
Email
lightbeam1100@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is currently no plan to make deidentified individual participant data (IPD) available due to concerns regarding patient privacy, lack of infrastructure for secure data sharing, or institutional restrictions.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Title: A Comparative Analysis of Post-Operative Delirium Incidence: Sevoflurane vs. Propofol in Geriatric Patients Under General Anesthesia Details: This dataset comprises anonymized clinical trial data collected from 200 patients aged 60–90 years undergoing elective surgery under general anesthesia. It includes demographic information, anesthesia type, ASA status, comorbidities, surgery type, and Confusion Assessment Method (CAM) scores collected over seven postoperative days. Documents Included: Full Study Protocol (as above) Completed CRFs/Proforma (de-identified) CAM Scoring Logs Statistical Analysis Output (SPSS) Informed Consent Form Template Ethics Committee Approval Letter
When the data will become available and for how long
Availability: The data will become available six months post-study completion, anticipated to be by March 2026. Retention Period: The data and associated documents will be accessible for at least 5 years following publication (i.e., until March 2031), with possibility of extended availability based on public or institutional interest
To whom data/document is available
Access will be granted to: Researchers affiliated with recognized academic or clinical institutions Public health policy makers Graduate or postgraduate medical/anesthesia students Ethics-approved independent researchers
Under which criteria data/document could be used
Data use is contingent on: Purpose: Non-commercial, research and educational use only Signing of a Data Use Agreement (DUA) detailing: Prohibition of re-identification attempts Use of data strictly for the approved project Proper citation of original study IRB/Ethical Review approval from the applicant's institution (if applicable)
From where data/document is obtainable
Documents and datasets will be obtainable through the following channels: Primary contact: Principal Investigator (Dr. [Insert Name], Allied Hospital, Faisalabad) Institutional Repository: University of Health Sciences or affiliated hospital server (TBD) Publication Supplementary Material: Upon journal article acceptance and publication (journal TBD) Email request: irslan3310@gmail.com
What processes are involved for a request to access data/document
Initial Inquiry: Interested parties contact the Principal Investigator via email or institutional contact form. Submission of Request Form: Researchers complete a Data Request Form outlining: Affiliation Study objectives Ethical clearance documentation (if applicable) Duration of intended data use Review by Data Access Committee (DAC): Applications will be evaluated within 15 working days. Data Use Agreement (DUA): Approved users must sign the DUA before receiving access credentials or files. Data Delivery: Data shared via encrypted institutional cloud storage or secure USB handover (if local). Follow-Up Reporting: Users agree to provide a summary or citation of how the data was used (e.g., in publications, presentations, or theses)
Comments