ISRCTN12170320 https://doi.org/10.1186/ISRCTN12170320

Exploration of the effects of fospropofol disodium in anesthesia induction for elderly hip surgery

Submission date 18/06/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 24/06/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 23/06/2025	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looked at two medications,fospropofol disodium and etomidate. To determine whether fospropofol disodium can be effectively and safely used for anesthetic induction in elderly patients undergoing hip surgery.To assess whether fospropofol disodium provides superior hemodynamic stability compared to etomidate during anesthetic induction in elderly hip surgery patients.To compare the incidence of adverse events between fospropofol disodium and etomidate, specifically evaluating injection pain, myoclonus, and adrenal suppression.

Who can participate?
Elderly patients (65-74 years), BMI 18-27 kg/m², ASA physical status I-III, scheduled for hip surgery under general anesthesia requiring endotracheal intubation.

What does the study involve?
Participants were randomly placed into two groups. One group received fospropofol disodium, the other received etomidate

What are the possible benefits and risks of participating?
To optimize anesthetic induction and intraoperative management by maintaining hemodynamic stability, minimizing adverse events, simplifying medication regimens (including reduced maintenance doses), shortening recovery time, and accelerating postoperative rehabilitation. As a water-soluble formulation, fospropofol disodium effectively mitigates injection pain, myoclonus, nausea/vomiting, and other adverse reactions, providing superior induction experience for patients.

Where is the study run from?
The First People's Hospital of Changzhou (China)

When is the study starting and how long is it expected to run for?
June 2025 to April 2026

Who is funding the study?
The First People's Hospital of Changzhou (China)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Randomized controlled trial of fospropofol disodium versus etomidate for anesthetic induction in elderly patients undergoing hip surgery: a randomized controlled trial

Acronym
FDE-HF

Study objectives
Fospropofol disodium demonstrates safe and effective application for anesthetic induction in elderly patients undergoing hip surgery. Compared with the commonly used clinical induction

agent etomidate, it provides greater hemodynamic stability, more effectively suppresses intubation-induced stress responses, and exhibits a lower incidence of complications such as myoclonus and injection pain.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/05/2025, Ethics Committee of First People's Hospital of Changzhou (The First People's Hospital of Changzhou, Changzhou, 213000, China; +86 519-68870965; czyygcp@czfph.com), ref: 2025 CL059

Study design
Single-centre single-blinded prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Elderly hip surgery patients

Interventions
Patients were randomly allocated into two groups (1:1 ratio) using a computer-generated randomisation list created by an independent biostatistician before patient enrolment. Block randomisation was not used. Allocation was concealed, and both patients and outcome assessors were blinded to group assignments.

Patients were randomly assigned to receive either intraoperative Fospropofol disodium infusion (10 mg/kg) or Etomidate infusion (0.3 mg/kg)

The treatment duration is defined as the time from anesthesia induction until discharge from the post anesthesia care unit (PACU), and the follow-up period is 48 hours postoperatively

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fospropofol disodium, etomidate

Primary outcome measure
Time to loss of consciousness, measured by recording the interval from drug injection until both disappearance of the eyelash reflex and failure to respond to verbal command on two consecutive attempts

Secondary outcome measures
1. Hemodynamic parameters including heart rate, systolic, diastolic, and mean arterial pressure are measured using noninvasive monitoring at before induction of anesthesia, loss of consciousness ,immediately after tracheal intubation ,surgical incision,20 minutes after surgical incision
2. Side effects including postoperative nausea and vomiting are documented based on clinical observation and medication use within the first 24 hours
3. Recovery Time is recorded based on the time to extubation time after surgery
4. postoperative delirium is measured using a Confusion Assessment Method scale at 48 hours postoperatively
5. Success rate of anesthesia induction is measured using counting successful inductions as a proportion of the total number of participants in each group
6. Incidence of injection pain and myoclonus within 30 seconds of initial dose administration are documented based on clinical observation
7. Total dosage of sufentanil, remifentanil, propofol, and vasoactive drugs used is measured using data obtained from the intravenous device

Overall study start date
16/02/2025

Completion date
16/04/2026

Eligibility

Key inclusion criteria
1.Elderly patients (65-74 years)
2.BMI 18-27 kg/m²
3.ASA physical status I-III
4.Scheduled for hip surgery under general anesthesia requiring endotracheal intubation

Participant type(s)
Patient

Age group
Adult

Lower age limit
65 Years

Upper age limit
74 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Refusal of general anesthesia
2. Allergy to general anesthetics
3. Preoperative cognitive impairment or significant hepatic/renal dysfunction
4. Baseline blood pressure ≥180/110 mmHg or ≤90/60 mmHg
5. Symptomatic cardiovascular, cerebrovascular, or respiratory diseases
6. Scheduled for bilateral joint surgery
7. Revision arthroplasty
8. Polytrauma
9. History of systemic or regional anesthesia within 3 months

Date of first enrolment
20/06/2025

Date of final enrolment
20/10/2025

Locations

Countries of recruitment
China

Study participating centre
The First People's Hospital of Changzhou
Changzhou
China
213000

Sponsor information

Organisation
The First People's Hospital of Changzhou

Sponsor details
The First People's Hospital of Changzhou
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Sponsor type
Hospital/treatment centre

Website
http://www.czfph.com/default.asp

ROR
https://ror.org/01gaj0s81

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The First People's Hospital of Changzhou

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
20/06/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from (Lan Qiu ,email address qiulanmz@163.com)

IPD sharing plan summary
Available on request