

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: August 21, 2026

ClinicalTrials.gov ID: NCT07450495

Study Identification

Unique Protocol ID: EC20240514(3)-P38
Brief Title: Effect of Different Concentrations of Sevoflurane for Anesthesia Induction in Pediatric Ophthalmic Surgery (SEVO-PED)
Official Title: Effectiveness and Safety of 6% Versus 8% Sevoflurane for Anesthesia Induction in Pediatric Ophthalmic Minor Surgery: A Randomized Controlled Trial
Secondary IDs:

Study Status

Record Verification: February 2026
Overall Status: Completed
Study Start: February 25, 2025 [Actual]
Primary Completion: February 25, 2026 [Actual]
Study Completion: February 26, 2026 [Actual]

Sponsor/Collaborators

Sponsor: Joint Shantou International Eye Center of Shantou University and the Chinese University of Hong Kong
Responsible Party: Principal Investigator
Investigator: Laiwen Lv [LLv]
Official Title: Principal Investigator
Affiliation: Joint Shantou International Eye Center of Shantou University and the Chinese University of Hong Kong
Collaborators:

Oversight

U.S. FDA-regulated Drug: No
U.S. FDA-regulated Device: No
U.S. FDA IND/IDE: No
Human Subjects Review: Board Status: Approved
Approval Number: EC20240514(3)-P38
Board Name: Ethics Committee of Joint Shantou International Eye Center, Shantou University and The Chinese University of Hong Kong
Board Affiliation: Joint Shantou International Eye Center, Shantou University and The Chinese University of Hong Kong

Phone: 0754-88393516
Email: yxllwyh@isiec.org
Address:

Joint Shantou International Eye Center of Shantou University and The
Chinese University of Hong Kong

City:

Shantou

State/Province:

Guangdong

Country:

China

Data Monitoring: No

Study Description

Brief Summary: This randomized controlled trial aims to compare the effectiveness and safety of 6% versus 8% sevoflurane inhalation induction in pediatric patients undergoing minor ophthalmic surgery. The primary outcome is emergence agitation assessed using the Pediatric Anesthesia Emergence Delirium (PAED) scale. Secondary outcomes include hemodynamic parameters, induction time, recovery time, and adverse events.

Detailed Description:

Conditions

Conditions: Chalazion

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 80 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Sevoflurane 8% Group	Drug: Sevoflurane

Arms	Assigned Interventions
Participants received 8% sevoflurane inhalation for anesthesia induction via face mask.	Sevoflurane inhalation anesthesia was used for induction and maintenance of general anesthesia in pediatric patients undergoing minor ophthalmic surgery. Other Names: • Sevoflurane, Sevoflurane, Ultane
Experimental: Sevoflurane 6% Group Participants received 6% sevoflurane inhalation for anesthesia induction via face mask.	Drug: Sevoflurane Sevoflurane inhalation anesthesia was used for induction and maintenance of general anesthesia in pediatric patients undergoing minor ophthalmic surgery. Other Names: • Sevoflurane, Sevoflurane, Ultane

Outcome Measures

Primary Outcome Measure:

1. PAED score

Measured using the Pediatric Anesthesia Emergence Delirium (PAED) scale. The PAED scale ranges from 0 to 20, with higher scores indicating more severe emergence delirium (worse outcome).

[Time Frame: Within 30 minutes after recovery]

Secondary Outcome Measure:

2. Induction time

Time from face mask placement to loss of eyelash reflex, measured in seconds.

[Time Frame: Immediately after anesthesia induction]

3. Recovery time

Time from discontinuation of sevoflurane to full recovery of consciousness, measured in minutes.

[Time Frame: Immediately after anesthesia discontinuation]

4. Minimum alveolar concentration (MAC)

Minimum alveolar concentration (MAC) values recorded during anesthesia maintenance.

[Time Frame: Perioperatively]

5. Respiratory depression

Incidence of respiratory depression recorded during the perioperative period.

[Time Frame: Perioperatively]

6. Hypoxia

Incidence of hypoxia recorded during the perioperative period.

[Time Frame: Perioperatively]

7. Cough

Incidence of cough recorded during the perioperative period.

[Time Frame: Perioperatively]

8. Nausea and vomiting

Incidence of nausea and vomiting recorded during the postoperative recovery period.

[Time Frame: Immediately after anesthesia until discharge]

Eligibility

Minimum Age: 1 Years

Maximum Age: 6 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Children aged 1 to 6 years (12–72 months)
- Scheduled to undergo minor ophthalmic surgery (e.g., chalazion excision) under general anesthesia
- American Society of Anesthesiologists (ASA) physical status I
- Assessed as suitable for inhalation anesthesia by anesthesiologists
- Written informed consent obtained from parents or legal guardians

Exclusion Criteria:

- ASA physical status II or higher
- Known hepatic or renal dysfunction
- Congenital heart disease
- History of malignant hyperthermia
- Known allergy to sevoflurane
- History of asthma or severe respiratory disease
- Upper respiratory tract infection within the past 4 weeks
- Anticipated difficult airway
- Refusal of participation by parents or legal guardians

Contacts/Locations

Central Contact Person: Laiwen Lv, MSc.

Telephone: 13750440405

Email: llw@jsiec.org

Central Contact Backup:

Study Officials:

Locations: **China, Guangdong**

Joint Shantou International Eye Center of Shantou University and The Chinese University of Hong Kong

Shantou, Guangdong, China, 515041

Contact: Laiwen Lv, MSc. 13750440405 llw@jsiec.org

Joint Shantou International Eye Center of Shantou University and The Chinese University of Hong Kong

Shantou, Guangdong, China, 515041

Contact: Laiwen Lv, MSc. 13750440405 llw@jsiec.org

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information:

[U.S. National Library of Medicine](#) | [U.S. National Institutes of Health](#) | [U.S. Department of Health & Human Services](#)