

Using remimazolam and sevoflurane together for children's adenoid surgery

Submission date 27/03/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/04/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/03/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Anesthesia management plays a crucial role in pediatric surgeries. Given the younger age, incomplete physical development, and weaker resistance of children, the incidence of anesthesia-related complications and mortality remains relatively high. Choosing an appropriate anesthesia plan is not only essential for the smooth progress of the surgery but also directly affects postoperative recovery and long-term prognosis. This study aims to explore the clinical application effects of different doses of benzenesulfonate remimazolam combined with sevoflurane in pediatric adenoidectomy using plasma radiofrequency ablation.

Who can participate?

Children who underwent plasma radiofrequency adenoidectomy.

What does the study involve?

The children were divided into four groups: A, B, C, and D, with 64 individuals in each group. Anesthesia induction was performed using sufentanil and other drugs. After intubation, groups B, C, and D were continuously infused with benzenesulfonate remimazolam at rates of 0.4 mg/kg/h, 0.6 mg/kg/h, and 0.8 mg/kg/h, respectively.

What are the possible benefits and risks of participating?

1. In pediatric adenoidectomy using plasma radiofrequency ablation, the combination of benzenesulfonate remimazolam and sevoflurane shows significant clinical effects. Continuous infusion of remimazolam at 0.6 mg/kg/h effectively reduces the incidence of emergence delirium, alleviates postoperative pain, and enhances parental satisfaction, without extending the PACU stay or increasing adverse events.

2. Adverse reactions included dizziness, hallucinations, restlessness, laryngospasm, nausea and vomiting, hypertension (an increase in mean arterial pressure of more than 30% above baseline), and tachycardia (heart rate >120 beats per minute).

Where is the study run from?

Gaoming District People's Hospital of Foshan, China

When is the study starting and how long is it expected to run for?

January 2024 to June 2025

Who is funding the study?

Gaoming District People's Hospital of Foshan, China

Who is the main contact?

Dr Min Wang, wangminee@126.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Min Wang

Contact details

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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

Clinical application study of different doses of remimazolam combined with sevoflurane in pediatric adenoidectomy

Study objectives

To explore the clinical application effects of different doses of benzenesulfonate remimazolam combined with sevoflurane in pediatric adenoidectomy using plasma radiofrequency ablation.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 02/07/2020, Ethics Committee of Gaoming District People's Hospital (No.1 Kangning Road, Hecheng Street, Gaoming District, Foshan, 528000, China; +86 0757-88667996; renshi6007@163.com), ref: 2020117

Study design

A single-center prospective randomized controlled study

Primary study design

Interventional

Secondary study design

Study setting(s)

Hospital

Study type(s)

Safety

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Anesthesia management in pediatric adenoidectomy using plasma radiofrequency ablation

Interventions

A single-center, prospective, randomized controlled study was conducted, selecting 256 children who underwent plasma radiofrequency adenoidectomy at Gaoming District People's Hospital in Foshan City from January 2024 to June 2025. The children were randomly divided into four groups, A, B, C, and D, with 64 individuals in each group according to the random number table method. Anesthesia induction was performed using sufentanil and other drugs. After intubation, groups B, C, and D were continuously infused with benzenesulfonate remimazolam at rates of 0.4 mg/kg/h, 0.6 mg/kg/h, and 0.8 mg/kg/h, respectively.

1. All children were routinely fasted for 8 hours and restricted from drinking for 4 hours. The modified Yale Preoperative Anxiety Scale (m-YPAS) was used to assess preoperative anxiety in the waiting area before surgery. On the day of surgery, intravenous access was established and fluids were administered as needed. Routine monitoring of vital signs was conducted after entering the operating room.

2. Grouping: Children in groups A, B, C, and D were all induced with sufentanil 0.3 µg/kg, benzenesulfonate remimazolam 0.3 mg/kg, benzenesulfonic acid rocuronium injection 0.15 mg/kg, and atropine 0.1 mg/kg for intravenous anesthesia induction. After successful intubation, groups B, C, and D immediately started continuous infusion of benzenesulfonate remimazolam at rates of 0.4 mg/kg/h, 0.6 mg/kg/h, and 0.8 mg/kg/h, respectively, and were maintained with sevoflurane inhalation. The control group A received an equal volume of 0.9% normal saline. The Bispectral Index (BIS) value was maintained between 40 and 60 throughout the procedure.

3. The surgical incision was made after the Minimum Alveolar Concentration (MAC) of sevoflurane was stabilized at 0.65. All vital signs were monitored and reported to the attending anesthesiologist. During the trial, in cases of hypotension, ephedrine 0.1 mg/kg was administered; for bradycardia, atropine 0.01 mg/kg was given; and for any psychiatric symptoms, comfort and symptomatic treatment were provided.

Intervention Type

Drug

Pharmaceutical study type(s)

Dose response

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Sufentanil, benzenesulfonate remimazolam, benzenesulfonic acid rocuronium, atropine, sevoflurane

Primary outcome measure

1. Anesthesia effects: Anesthesia time, awakening time (the interval from cessation of inhalation anesthesia to eye-opening on verbal command), and PACU stay time measured using data collected from patient medical records at one time point
2. ED situation: Emergence delirium measured using the Pediatric Anesthesia Emergence Delirium (PAED) scale, which includes five items: eye contact, purposeful movement, awareness of the surrounding environment, restlessness, and inconsolability after surgery
3. Postoperative pain intensity measured using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale every 10 minutes during the first 30 minutes in the PACU
4. Parental satisfaction was measured using self-reported data on a numerical rating scale (NRS, range 0-10) 24 hours after surgery
5. Adverse reactions included dizziness, hallucinations, restlessness, laryngospasm, nausea and vomiting, hypertension (an increase in mean arterial pressure of more than 30% above baseline), and tachycardia (heart rate >120 beats per minute) measured using data collected from case reports at one time point
6. Behavioral changes three days after surgery measured using the 27-item Post-Hospital Behavior Questionnaire (PHBQ) through telephone interviews on the third day after surgery

Secondary outcome measures

There are no secondary outcome measures.

Overall study start date

02/07/2020

Completion date

30/06/2025

Eligibility

Key inclusion criteria

1. ASA physical status I-II
2. Age 3-12 years
3. No difficult airway, Mallampati grade I-II
4. No upper respiratory tract infection in the past month
5. No neurological, cardiopulmonary, hepatic, or renal systemic diseases
6. Routine blood tests, coagulation function, electrolytes, hepatic and renal function tests, chest X-rays, and electrocardiograms show no significant abnormalities
7. Children scheduled for pediatric plasma radiofrequency adenoidectomy
8. Informed consent from the patient's family

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

256

Key exclusion criteria

Certainly! Here's the paragraph transformed into a numbered list:

1. BMI ≥ 25 kg/m²
2. Upper respiratory tract infection, cardiopulmonary insufficiency within one month
3. Perioperative allergies
4. Unpredicted difficult airway
5. Failed intubation on the first attempt
6. Severe complications in children, such as hemorrhagic shock, anaphylactic shock, cardiac arrest, etc.
7. Changes in surgical or anesthesia plans due to medical conditions
8. Withdrawal from the study at the request of the patient's family
9. Loss to follow-up of the subjects

Date of first enrolment

01/01/2024

Date of final enrolment

31/01/2025

Locations

Countries of recruitment

China

Study participating centre

Gaoming District People's Hospital of Foshan

No.1 Kangning Road, Hecheng Street, Gaoming District

Foshan

China

528000

Sponsor information

Organisation

Gaoming District People's Hospital in Foshan

Sponsor details

No.1 Kangning Road, Hecheng Street, Gaoming District

Foshan

China

528000

Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Gaoming District People's Hospital of Foshan

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

30/06/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Min Wang, wangminee@126.com

IPD sharing plan summary

Available on request