ISRCTN67586415 https://doi.org/10.1186/ISRCTN67586415

Using remimazolam and sevoflurane together for children's adenoid surgery

Submission date
27/03/2025

Recruitment status
No longer recruiting

Registration date
01/04/2025

Overall study status
Completed

Last Edited
31/03/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
No.1 Kangning Road, Hecheng Street, Gaoming District
Foshan
China
528000
+86 1818883097
wangminee@126.com

Additional identifiers

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

Primary study design
Interventional

Study design

A single-center prospective randomized controlled study

Study type(s)
Safety

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

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sufentanil, benzenesulfonate remimazolam, benzenesulfonic acid rocuronium, atropine, sevoflurane

Primary outcome(s)
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

Key secondary outcome(s)
There are no secondary outcome measures.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
12 Years

Sex
All

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Gaoming District People's Hospital of Foshan

Results and Publications

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