ISRCTN68396064 https://doi.org/10.1186/ISRCTN68396064

Improvement and clinical benefit analysis of low-dose esketamine on postoperative pain and sleep after sinus surgery

Submission date
21/11/2025

Recruitment status
No longer recruiting

Registration date
01/12/2025

Overall study status
Completed

Last Edited
27/11/2025

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Zi-ping Zhang

Contact details
Guangzhou Twelfth People's Hospital
Guangzhou
China
510000
+86 20-38981288
zhangzp202511@126.com

Additional identifiers

Study information

Scientific Title
Effects of esketamine on postoperative pain and sleep

Study objectives
To investigate the benefits of low-dose esketamine for pain relief and sleep quality improvement after sinus surgeryand stable hemodynamics during perioperative period.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/07/2021, The Human Research Ethics Committee of the Guangzhou Twelfth People's Hospital (Guangzhou Twelfth People's Hospital, Guangzhou, 510000, China; +86 20-38661509; srx8255@163.com), ref: 2021059

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Dose comparison

Assignment
Sequential

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Sinusitis and were scheduled to undergo functional endoscopic sinus surgery

Interventions
All patients were required to abstain from food for at least 6 hours and liquids for 2 hours before surgery. Intravenous access was established, and electrocardiogram (ECG), heart rate (HR), pulse oximetry, blood pressure (BP), and bispectral index (BIS) were monitored before induction of anesthesia.

The anesthesia protocol was as follows: prior to induction, patients received an intravenous injection of either physiological saline (control group), 0.2 mg/kg ketamine, or 0.3 mg/kg ketamine. Each solution was prepared in a syringe with a volume of 3.0 ml, and one was randomly assigned for use during induction using the online random number table method.

Anesthesia was then induced with intravenous injection of 0.1 mg/kg propofol medium/long-chain fat emulsion (1.0–2.0 mg/kg), 0.5 μg/kg sufentanil, and 0.2 mg/kg cisatracurium. After intubation under visual laryngoscopy, patients were connected to an anesthesia machine for mechanical ventilation. Ventilator parameters were adjusted according to patient condition, maintaining end-tidal carbon dioxide between 35 and 45 mmHg. Cisatracurium was administered intermittently during surgery. For anesthesia maintenance, patients received inhalation of 1.0–3.0 VOL% sevoflurane (0.65–1.70 times the minimum alveolar concentration [MAC]) and 2.0–6.0 mg/kg/h propofol, with BIS maintained between 40 and 60. Blood pressure was controlled to achieve a 20% reduction from baseline, using nitroglycerin or vasopressors if necessary. General

anesthesia drugs were discontinued near the end of surgery. All patients received anesthesia from the same team of anesthesiologists. Postoperative data were collected by an anesthesiologist specializing in data collection. The anesthesiologist, physician, and patients were blinded to group assignments during data collection.

Intervention Type
Mixed

Primary outcome(s)
1. Pain measured using visual analogue scale (VAS) at before and after treatment

2. Sleep measured using Pittsburgh Sleep Quality Index (PSQI) at before and after treatment

3. Depression measured using Hamilton Depression Rating Scale (HAM-D) at before and after treatment

4. Anxiety measured using Hamilton Anxiety Rating Scale (HAM-A) at before and after treatment

5. Psychological resilience measured using Connor-Davidson Resilience Scale (CD-RISC) at before and after treatment

6. Quality of life measured using Sino-Nasal Outcome Test 20 (SNOT-20) (Chinese version) at before and after treatment

Key secondary outcome(s))

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Those who were 18 to 70 years old
2. Those without severe cardiovascular, respiratory, hepatic, or renal diseases
3. Those with a preoperative American Society of Anesthesiologists (ASA) classification of I to III
4. Those whose operation time was between 8 am and 6 pm
5. Those without a history of peptic ulcer disease
6. Those without a history of addiction to analgesic drugs
7. Those without a history of migraine disease
8. Those who could cooperate with physical examination and pain assessment

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit

70 years

Sex
All

Total final enrolment
135

Key exclusion criteria
1. Had an operative time of less than 1 hour or more than 3 hours
2. Had an operative bleeding volume of more than 200 ml
3. Patients with intracranial hypertension
4. Psychiatric patients such as schizophrenia, delusional disorders, and epilepsy
5. Patients with severe liver and renal conditions
6. Did not cooperate with postoperative treatment and follow-up visits
7. Allergies to the study medications or developed severe infections after surgery

Date of first enrolment
22/07/2021

Date of final enrolment
23/06/2022

Locations

Countries of recruitment
China

Sponsor information

Organisation
Twelfth Guangzhou City People's Hospital

ROR
https://ror.org/03hm7k454

Funder(s)

Funder type

Funder Name
Guangzhou Municipal Science and Technology Project

Alternative Name(s)

Guangzhou Science and Technology Foundation, Guangzhou Science and Technology Plan, Sci-Tech Project Foundation of Guangzhou City, Science and Technology Program of Guangzhou City

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available