Items from the Chinese Clinical Trial Registry (ChiCTR) Data Set (SPIRIT item 2b)

Data category	**Information**
Primary registry and trial identifying number	www.chictr.org.cn ChiCTR2300072522
Date of registration in primary registry	June 15, 2023
Secondary identifying numbers	RF-TEA
Source (s) of monetary or material support	Phase II Clinical Research Program of the First Affiliated Hospital of Zhejiang University School of Medicine (No. BL202234, to YYX)
Primary sponsor	The First Affiliated Hospital of Zhejiang University School of Medicine
Secondary sponsor (s)	/
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Public title	Therapeutic effect of small-dose remifentanil infusion on severe emergence agitation after general anesthesia for major abdominal surgery in adults
Scientific title	Therapeutic effect of small-dose remifentanil infusion on severe emergence agitation after general anesthesia for major abdominal surgery in adults: Study protocol for a randomized and controlled trial (RF-TEA Trial)
Countries of recruitment	China
Health condition(s) or problem (s) studied	Emergence agitation after general anesthesia
Intervention (s)	***Intervention Name:*** Remifentanil group ***Intervention Description:*** Once severe emergence agitation occurs, the participant assigned to remifentanil group will be given remifentanil 1 μg/kg by intravenous injection, followed by infusion at 0.1 μg/kg·min. ***Intervention Name:*** Normal saline group ***Intervention Description:*** Once severe emergence agitation occurs, the participant assigned to normal saline group will be administered the same volume of normal saline.

Data category	Information
Key inclusion and exclusion criteria	***Inclusion criteria:*** • Adult patients aged 18-75 years with ASA I~III who developed severe EA after general anesthesia with informed consent. ***Exclusion Criteria:*** • Inability to communicate properly before surgery. • History of mental diseases with the long-term use of psychotropic drugs. • Central nervous system disease (e.g., dementia, Parkinson's disease). • History of allergy to propofol, opioids or abuse of opioids.
Study type	Interventional ***Allocation:*** randomized ***Intervention model:*** parallel ***Masking:*** Blind to anesthesiologists in OR and PACU, CRC, patients, nurses, follow-up participants, investigators, statisticians. ***Primary purpose:*** recovery quality after general anesthesia research
Date of first enrolment	July 24, 2023
Target sample size	80
Recruitment status	Enrolling
Primary outcome(s)	EA recurrence rate of severely agitated patients after intervention in the PACU
Key secondary outcomes	• Recurrent EA and RSAS scores when EA reoccurred during intervention; • The time to regain consciousness, time to extubation and duration of PACU stay; • Comfort during extubation as evaluated by the grade of cough; • The awake quality and cognitive scores at 5 min and 30 min after extubation; • The adverse events after intervention in the PACU, including hypoxemia, bradycardia and hypotension; • Total amount of propofol, opioid drugs and other rescue drugs required after extubation in the

	PACU; • The cognitive scores at 24, 48 and 72 hours after operation using the MoCA 5-min and 3D-CAM test.
Ethics Review	• Status: Approved • Date of approval: October 19, 2022 • Name and contact details of ethics committee (s): Clinical Research Ethics Committee of the First affiliated Hospital, College of Medicine, Zhejiang University
Completion date	• We expect to complete the study on December 31, 2024.
Summary Results	• /
IPD sharing statement	• The data that support the findings of this study will be available from the corresponding author upon reasonable request.