

# The effects of remimazolam and dexmedetomidine on emotion, cognitive function, and neuroprotection in patients with ischemic stroke

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		<input type="checkbox"/> Protocol
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		<input type="checkbox"/> Results
<b>Last Edited</b> 13/04/2026	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

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## **Additional identifiers**

Xinjiang "Tianshan Talents" Training Program, Medical and Health High-Level Talent Project:  
"Research on Key Technologies for Prevention and Treatment of Perioperative Important Organ  
Dysfunction in Elderly Patients" Project Number  
TSYC202401A003

## **Study information**

### **Scientific Title**

Clinical effects of remimazolam and dexmedetomidine on emotion, cognitive function, and  
neuroprotection in patients with ischemic stroke

### **Study objectives**

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 25/11/2025, Ethics Committee for Clinical Research, People's Hospital of Xinjiang  
Uygur Autonomous Region (No. 91 Tianchi Road, Tianshan District, Urumqi City, Xinjiang Uygur  
Autonomous Region, People's Hospital of Xinjiang Uygur Autonomous Region, Urumqi, 830011,  
China; +86 0991-856 8013; -), ref: KY2025112417

### **Primary study design**

Interventional

### **Allocation**

Randomized controlled trial

### **Masking**

Blinded (masking used)

### **Control**

Active

## Assignment

Sequential

## Purpose

Prevention

## Study type(s)

## Health condition(s) or problem(s) studied

Patients with ischemic stroke

## Interventions

### 1. Preoperative Assessment (24 h Before Surgery)

Anxiety and depression were evaluated using HADS-A and HADS-D. Cognitive function was assessed by MoCA and MMSE. Neurological impairment was scored with NIHSS. Serum indicators, including cathepsin S (CTSS), inflammatory factors (IL-6, TNF- $\alpha$ , CRP), neuronal injury markers (S-100 $\beta$ , NSE), neurotransmitters (NE, 5-HT), and BDNF, were detected.

### 2. Study Design and Anesthesia Protocols

This was a randomized controlled trial (RCT) with a double-blind design. Randomization was performed using a computer program and sealed envelopes. Patients with ischemic stroke were randomly divided into three groups: remimazolam group (RM), dexmedetomidine group (Dex), and control group (C).

All patients received general anesthesia with tracheal intubation. Group RM: Induction with remimazolam 0.2 mg/kg iv; maintenance with remimazolam 0.2–0.5 mg·kg<sup>1</sup>·h<sup>1</sup> (BIS 40–60), discontinued 30 min before surgery. Group Dex: Loading dose of dexmedetomidine 0.5  $\mu$ g/kg iv 10 min before induction; maintenance with 0.2  $\mu$ g·kg<sup>1</sup>·h<sup>1</sup> (BIS 40–60), discontinued 30 min before surgery. Group C: Routine propofol-based anesthesia without remimazolam or dexmedetomidine.

Anesthesia induction: Propofol 2–3 mg/kg, sufentanil 0.5  $\mu$ g/kg, cisatracurium 0.15 mg/kg iv; orotracheal intubation (depth 22–24 cm) followed by mechanical ventilation (FiO<sub>2</sub> 30%, RR 10–12 breaths/min, I:E 1:2–2.5, VT 8–12 mL/kg, ETCO<sub>2</sub> 35–45 mmHg). Anesthesia maintenance: Propofol 4–12 mg·kg<sup>1</sup>·h<sup>1</sup> and remifentanyl 0.2  $\mu$ g·kg<sup>1</sup>·h<sup>1</sup> iv; additional sufentanil 0.2  $\mu$ g/kg before skin incision; BIS maintained at 40–60, with dosage adjusted according to vital signs. Fluid therapy included lactated Ringer's solution and 6% hydroxyethyl starch.

Anesthesia emergence: Neuromuscular blockade reversed with atropine 0.5 mg and neostigmine 0.05–0.07 mg/kg iv; tracheal extubation when meeting extubation criteria; patients transferred to the ward when recovery score  $\geq$ 6 with clear consciousness and no nausea/vomiting. All patients received standard secondary stroke prevention and rehabilitation (physical therapy + cognitive behavioral intervention) postoperatively, with benzodiazepines avoided.

### 3. Outcome Measures

Vital signs (MAP, HR, SpO<sub>2</sub>) were recorded at preoperative induction, surgery start, post-thrombectomy, postoperative immediately, 6 h, 12 h, 24 h and 48 h. Adverse events and mental status were documented.

Follow-up indicators: HADS-A/HADS-D (1 d, 3 d, 7 d postoperatively and discharge); MoCA/MMSE (3 d, 7 d postoperatively); VAS pain scores (2 h, 12 h, 1 d, 3 d postoperatively); serum CTSS, IL-6, TNF- $\alpha$ , CRP, S-100 $\beta$ , NSE, NE, 5-HT, BDNF and NIHSS scores (24 h, 3 d, 7 d postoperatively). Long-

term follow-up (1, 3, 6 months postoperatively) was performed via online platforms to assess anxiety, depression, cognitive function and NIHSS scores.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Remimazolam, dexmedetomidine

### **Primary outcome(s)**

1. Cognitive function measured using the Mini-Mental State Examination (MMSE) and Montreal Cognitive Assessment (MoCA) at preoperatively, 3, 7, 30 and 90 days postoperatively

### **Key secondary outcome(s)**

1. Neurological function impairment measured using the NIH Stroke Scale/Score (NIHSS) at preoperatively, 3, 7, 30 and 90 days postoperatively

2. Serum levels of cathepsin S (CTSS), interleukin-6 (IL-6), C-reactive protein (CRP), tumour necrosis factor alpha (TNF- $\alpha$ ), S100 calcium-binding protein beta (S100- $\beta$ ), norepinephrine (NE), 5-hydroxytryptamine (5-HT), and brain-derived neurotrophic factor (BDNF) measured using enzyme-linked immunosorbent assay (ELISA) at preoperatively, at the end of surgery and 3 days postoperatively

3. Anxiety and depression measured using the Hospital Anxiety and Depression Scale-Anxiety (HADS-A) and HADS-depression (HADS-D) at 1, 3, 30 and 90 days postoperatively

### **Completion date**

31/12/2026

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of acute anterior circulation ischemic stroke (internal carotid artery / M1–M2 segment of middle cerebral artery), with penumbra confirmed by CTP/MRP
2. Age 18–80 years, no gender restriction, ASA physical status I–III
3. Admission within 24 hours of symptom onset
4. NIHSS score 4–15 (mild-to-moderate neurological injury[7]), mRS score  $\leq 4$
5. No preoperative history of anxiety/depression (HADS score  $\leq 7$ ) or cognitive impairment (MoCA  $\geq 26$ , MMSE  $\geq 24$ )
6. Prior to the study, the patient or legal representative understood and voluntarily signed the informed consent approved by the ethics committee, agreed to randomization, and cooperated with follow-up

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

80 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Diagnosis of global aphasia, transient ischemic attack, visual or auditory impairment, or severe dementia (MMSE < 17, unable to complete scales)
2. Patients with severe uncontrolled medical conditions including diabetes mellitus, hypertension, heart disease, chronic active viral hepatitis, or a history of schizophrenia and other psychiatric disorders; patients receiving preoperative anxiolytics or antidepressants
3. Abnormal hepatic or renal function, severe arrhythmia, bradycardia, or major organ failure such as decompensated cardiopulmonary failure
4. Intraoperative blood loss  $\geq$  300 mL
5. Patients requiring intraoperative blood transfusion
6. Operation duration  $\geq$  3 hours
7. Hypersensitivity to remimazolam, dexmedetomidine (DEX), or  $\alpha_2$  agonists
8. Exclusion by neuroimaging: large-area infarction (ASPECTS score < 6 or infarct core volume > 70 mL); complicated with intracranial hemorrhage (type PH2 hematoma) or mass effect
9. Anesthesia-related exclusion: difficult airway, severe intraoperative hypotension (MAP < 60 mmHg for > 10 minutes), or requirement for high-dose vasoactive drugs

**Date of first enrolment**

01/12/2025

**Date of final enrolment**

13/04/2026

**Locations**

**Countries of recruitment**

China

**Sponsor information**

**Organisation**

People's Hospital of Xinjiang Uygur Autonomous Region

ROR

https://ror.org/02r247g67

## Funder(s)

### Funder type

### Funder Name

Government of Xinjiang Uygur Autonomous Region of China

### Alternative Name(s)

, People's Government of Xinjiang Uygur Autonomous Region, Xinjiang Uygur Autonomous Region Government, The Government of Xinjiang Uygur Autonomous Region of China

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

China

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		18/06/2025	13/04/2026	No	Yes