

Effect of oliceridine on stress response in mechanically ventilated ICU patients

Submission date 14/08/2026	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/08/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 28/08/2026	Condition category Signs and Symptoms	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Effect of oliceridine on stress response in mechanically ventilated ICU patients: a randomized controlled trial

Study objectives

This study aims to investigate the efficacy and safety of oliceridine, a novel G-protein–biased μ -opioid receptor agonist, for analgesia in mechanically ventilated ICU patients.

Ethics approval required

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Ethics approval(s)

Approved 27/08/2025, Scientific Research Ethics Committee of the First Affiliated Hospital of Jinan University (The First Affiliated Hospital of Jinan University, 613 Huangpu Avenue West, Guangzhou, 510632, China; +86 (0)38688217; ofyylbgs@jnu.edu.cn), ref: KY-2025-205

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Pain in mechanically ventilated patients

Interventions

This is a prospective, randomized, active-controlled, parallel-group interventional study. Participants are randomly assigned in a 1:1 ratio to receive either oliceridine fumarate (intervention group) or remifentanyl hydrochloride (control group). Randomization is performed using a computer-generated random number table, with participants allocated to one of the two treatment arms in a 1:1 ratio.

In the intervention group, oliceridine fumarate is administered intravenously, with a loading dose of 0.03 mg/kg followed by a continuous maintenance infusion starting at 0.0018 mg/kg/min. The infusion rate may be titrated within a range of 0.0006 to 0.045 mg/kg/min according to clinical requirements.

In the control group, remifentanyl hydrochloride is administered intravenously, with a loading dose of 1 μ g/kg followed by a continuous maintenance infusion starting at 0.06 μ g/kg/min. The infusion rate may be titrated within a range of 0.02 to 0.15 μ g/kg/min as clinically indicated.

The study duration is from intubation to extubation.

Intervention Type

Drug

Phase

Phase III/IV

Drug/device/biological/vaccine name(s)

Oliceridine, remifentanyl

Primary outcome(s)

1. Total cortisol level measured using enzyme-linked immunosorbent assay (ELISA) at baseline and 1-2 days post-intervention, twice a day, at 8:00 AM and 4:00 PM

Key secondary outcome(s)

1. Inflammatory biomarkers, including IL-1 β , IL-6, TNF- α , measured using enzyme-linked immunosorbent assay (ELISA) at baseline and 1-2 days post-intervention

2. Duration of mechanical ventilation measured using the duration of mechanical ventilation from intubation to extubation at during mechanical ventilation

3. Length of stay measured using patient records at end of stay

4. Mortality measured using patient records at until hospital discharge or in-hospital death

5. Gastrointestinal dysfunction measured using the timing and frequency of flatulence, dry mouth, dyspepsia, diarrhea, and constipation using patient records at duration of treatment

Completion date

01/06/2028

Eligibility**Key inclusion criteria**

1. Adult ICU patients requiring endotracheal intubation with mechanical ventilation, and expected to need sedation and analgesia for >24 hours after randomization

2. Target sedation level within a Richmond Agitation-Sedation Scale (RASS) score of -3 to 0

3. Age $\geq$ 18 years and <80 years, regardless of sex

4. Body mass index (BMI) between 18 and 30 kg/m²

5. Patients or their legally authorized representatives fully understand the purpose and significance of the study, voluntarily agree to participate, and provide written informed consent

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. Known hypersensitivity or allergy to opioids or related agents
2. Receipt of sedation and analgesia for more than 3 consecutive days prior to informed consent, either in the ICU or on a general ward before ICU admission
3. Patients with any of the following medical histories or evidence of increased risk related to sedation/analgesia during the screening period:
 - 3.1. Neuropsychiatric disorders: Psychiatric diseases (e.g., schizophrenia, depression) or cognitive impairment; history of psychiatric or anesthetic drug abuse; history of alcohol abuse within 3 months prior to screening; history of illicit drug use; long-term use of psychotropic medications
 - 3.2. Severe hepatic or renal impairment, including patients on dialysis
 - 3.3. Neurological conditions: Status epilepticus, convulsions; traumatic brain injury, intracranial hypertension, cerebral aneurysm; Glasgow Coma Scale (GCS) score ≤ 12 ; high spinal cord injury or quadriplegia
 - 3.4. Life expectancy ≤ 48 hours
4. Pregnant or lactating women
5. Any other condition that, in the opinion of the investigator, renders the patient unsuitable for participation in this clinical trial

Date of first enrolment

01/02/2026

Date of final enrolment

01/02/2028

Locations**Countries of recruitment**

China

Sponsor information**Organisation**

Wu Jieping Medical Foundation

ROR

<https://ror.org/05dgwj702>

Funder(s)

Funder type

Funder Name

Wu Jieping Medical Foundation

Alternative Name(s)

, WJMF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available