

Research on analgesia in mechanically ventilated patients following abdominal surgery

Submission date 02/04/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/04/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/04/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Postoperative pain management is essential to enhance rapid recovery in critically ill abdominal surgical patients. However, the optimal choice of analgesic agents for this specific patient population remains debatable. This study aimed to compare the effects and safety of sufentanil versus fentanyl for analgesia in critically ill abdominal surgical patients requiring mechanical ventilation.

Who can participate?

Patients aged between 18 and 85 years undergoing abdominal surgery with an expected duration of mechanical ventilation of under 72 hours

What does the study involve?

This study will allocate enrolled patients into two groups receiving fentanyl or sufentanil for analgesia, respectively. The following parameters will be systematically documented: baseline parameters, analgesia and sedation quality. Daily spontaneous breathing trials (SBTs) will be recorded for an extubation readiness assessment. The study will collect outcome data and monitor adverse events until patient discharge from the ICU. Through prospective comparative analysis, this study will evaluate the relative safety and effects of fentanyl versus sufentanil for pain management in mechanically ventilated patients after abdominal surgery.

What are the possible benefits and risks of participating?

No direct risks or benefits.

Where is the study run from?

West China Hospital of Sichuan University, China

When is the study starting and how long is it expected to run for?

September 2016 to September 2022

Who is funding the study?

West China Hospital, Sichuan University, China

Who is the main contact?
Dr Yongfang Zhou, zyfmng@163.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Yongfang Zhou

Contact details

West China Hospital of Sichuan University, Guoxue Alley 37#, Wuhou District
Chengdu
China
610041
+86-028-85422506
zyfmng@163.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

The efficacy and safety of sufentanil versus fentanyl for analgesia in mechanically ventilated patients after major abdominal surgery: a randomized controlled study

Study objectives

This study aimed to compare the efficacy and safety of sufentanil versus fentanyl for analgesia in critically ill abdominal surgical patients requiring mechanical ventilation.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 29/09/2016, The Ethics Committee of West China Hospital of Sichuan University (Guoxue Alley 37#, Wuhou District, Chengdu, 610041, China; +86-028-85423237; huaxilunli@163.com), ref: 2016 (208)

Study design

Interventional randomized parallel-group controlled trial

Primary study design

Interventional

Study type(s)

Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied

Patients receiving mechanical ventilation after abdominal surgery

Interventions

A random sequence is computer-generated and concealed in consecutively numbered, sealed, opaque envelopes by one study team member. Another member of the study team will open the envelope before each assignment. Eligible patients will be randomly assigned in a 1:1 ratio to receive either sufentanil or fentanyl.

Analgesia in the sufentanil group

Intervention: sufentanil

Loading dose: 0.15-0.25 µg/kg

Continuous maintenance dose: 0.1-0.3 µg/kg/hour

The target analgesia level: CPOT score: 0 to 1

Analgesia in the sufentanil group

Intervention: fentanyl

Loading dose: 1.0-2.0 µg/kg

Continuous maintenance dose: 1.0-2.0 µg/kg/hour

The target analgesia level: CPOT score: 0 to 1

Sedation in both groups

Intervention: propofol or dexmedetomidine

Loading dose: 0.5-3.0 mg/kg(propofol), 0.5 µg/kg(dexmedetomidine)

Continuous maintenance dose: 0.5-3.0 mg/kg/hour(propofol), 0.2-0.7 µg/kg/hour (dexmedetomidine)

The target sedation level: RASS score: -2 to 0

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Sufentanil, fentanyl

Primary outcome(s)

Time from the cessation of sedation to awakening, defined as the recovery time, is measured using data collected from patient medical records at one-time point

Key secondary outcome(s))

The following secondary outcome measures are assessed using data collected from patient medical records at one time point:

1. Mechanical ventilation (MV) time, defined as the time from inclusion to extubation
2. Extubation time, defined as the time from the cessation of sedation to extubation
3. Duration of analgesia or sedation, defined as the time of study enrollment to the point of complete cessation of all pharmacological interventions in these categories
4. Duration of mechanical ventilation, defined as the time from intubation to extubation
5. Length of stay in the ICU, defined as the duration (in hours) from ICU admission to discharge, with admission and discharge time recorded to the nearest hour
6. Incidence of delirium: delirium occurrence was systematically monitored and recorded daily using the Confusion Assessment Method (CAM-ICU) by trained research staff
7. Abdominal distension, defined as the incidence of related adverse events (e.g. gastric retention, nausea, and vomiting): These events were prospectively documented for all patients from inclusion to ICU discharge
8. Incidence of related adverse events (e.g. gastric retention, nausea, and vomiting)

Completion date

30/09/2022

Eligibility

Key inclusion criteria

1. Patients receiving mechanical ventilation after abdominal surgery
2. Patients predicted to have a mechanical ventilation duration under 72 hours
3. Aged 18 - 85 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

85 years

Sex

All

Total final enrolment

190

Key exclusion criteria

1. Known or suspected allergies to analgesics
2. Pregnancy or lactation
3. Consciousness disorders secondary to:
 - 3.1. Metabolic diseases
 - 3.2. Neurovascular diseases
 - 3.3. Infections
 - 3.4. Brain trauma
4. Unstable hemodynamics
5. Myasthenia gravis
6. Use of monoamine oxidase inhibitors within 14 days prior to enrollment
7. Bradycardia or severe heart block

Date of first enrolment

01/12/2017

Date of final enrolment

30/09/2022

Locations

Countries of recruitment

China

Study participating centre

West China Hospital of Sichuan University

Guoxue Road 37#, Wuhou District

Chengdu

China

610041

Sponsor information

Organisation

West China Hospital of Sichuan University

ROR

<https://ror.org/007mrxy13>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

West China Hospital, Sichuan University

Alternative Name(s)

West China Hospital, West China School of Medicine and West China Hospital, Sichuan University, WCH, WCHSM/WCH

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date