ISRCTN82186642 https://doi.org/10.1186/ISRCTN82186642

Research on analgesia in mechanically ventilated patients following abdominal surgery

Submission date
02/04/2025

Recruitment status
No longer recruiting

Registration date
11/04/2025

Overall study status
Completed

Last Edited
10/04/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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, zyfmg@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
zyfmg@163.com

Additional identifiers

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)

Primary study design
Interventional

Study design
Interventional randomized parallel-group controlled trial

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, WCSM/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