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Protocol

Effectiveness of analgosedation protocol on duration of mechanical ventilation in adults with trauma: a pragmatic, cluster and randomized study

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ABSTRACT

Background: Sedation practices in trauma intensive care unit (ICU) patients requiring invasive mechanical ventilation (IMV) are still not well studied. While protocol-directed sedation (PDS) and spontaneous awakening trials (SAT) have improved outcomes in non-trauma groups, their use in trauma patients-who often experience higher pain levels, substance use, and complex injuries-is uncertain. Analgosedation, which gives priority to analgesics before sedatives, may have benefits in this group but has not been thoroughly tested in trauma ICUs.
Methods: This is a 24-month, single-center, pragmatic, cluster-randomized controlled trial with a crossover design comparing an analgosedation (+SAT) protocol to a traditional PDS+SAT protocol. Adult trauma ICU patients receiving IMV and expected to need continuous sedation for at least 48 hours are enrolled. The primary outcome is ventilator-free days at day 10 (VFD-10). Secondary outcomes include time to weaning, sedative and opioid exposure, delirium-and coma-free days, self-extubation, ICU/hospital length of stay, and mortality. Interventions are implemented throughout the ICU each month, with crossover randomization. A waiver of informed consent was granted due to the patient's incapacity and the minimal risk involved. Data will be analyzed using intention-to-treat principles and time-dependent Cox models to account for clinical confounders.
Conclusions: This trial aims to determine whether an analgosedation strategy improves clinically meaningful outcomes in mechanically ventilated trauma ICU patients compared to a traditional sedation approach. The findings will address a critical evidence gap and inform sedation protocols tailored to trauma populations, potentially enhancing recovery and decreasing ICU workload.
Trial registration: ClinicalTrials.gov Identifier: NCT05751863 Protocol version: 4.0.

Keywords: Sedation, Analgosedation, Mechanical ventilation, Trauma, Respiratory failure

INTRODUCTION

Adults in the ICU on IMV are often administered intravenous sedatives and opioids on a scheduled basis, either continuously or intermittently, to ensure comfort, aid care, and support ventilation.[1] However, these agents are frequently used at high doses and for a prolonged duration, which may delay IMV weaning and worsen outcomes. PDS with or without a spontaneous awakening trial (SAT) has been rigorously evaluated in non-trauma patients and has been shown to reduce IMV duration and delirium, and improve post-ICU outcomes.[1-6] However, patients admitted to the ICU with major trauma have distinct characteristics (vs. other ICU populations) that influence sedative choice, dosing, and response, including a higher prevalence of substance use disorders, frequent intracranial injuries, higher pain levels, and the need for repeat surgeries.[2,7-20] This raises important questions about whether traditional ICU sedation strategies that include nurse-managed PDS and SAT protocols are safe and effective in the ICU trauma population. Moreover, in the ICU trauma population, it remains unclear if analgosedation, where analgesic use is prioritized before sedatives, will lead to the same improved outcomes (i.e., improved pain control, reduced oversedation and delirium, and a reduced time to IMV liberation) demonstrated in non-trauma ICU trials.[6,21-25] We therefore plan a single-center cluster randomized controlled trial (RCT) to compare an analgosedation (+SAT) protocol to a traditional sedation (PDS+SAT) protocol in ICU adults with trauma to better inform sedation practices in this population and guide future multicenter RCTs.

Objectives

This pragmatic cluster (PC) RCT compares use of an analgosedation (SAT) protocol to use of a traditional sedation (PDS+SAT) protocol on the primary outcome of days free of IMV during the first 10 days of the ICU stay (VFD-10). It will also evaluate secondary outcomes, including time to IMV weaning, days free of delirium and coma-free during the ICU stay, daily ICU opioid and sedative exposure, psychotropic use, self-extubation, ICU/hospital length of stay, and mortality.

METHODS

Trial design

A 24-month, prospective, single-center, single crossover, PC-RCT (Figure 1). PC-RCTs are increasingly being used in the ICU setting to evaluate the efficacy and safety of multicomponent interventions like the analgosedation protocol being evaluated in our study.[26-28]

Study protocol was developed in accordance with SPIRIT (Standard protocol items: recommendations for interventional trials) recommendations.[29] Completed SPIRIT checklist is provided as additional file (Figure 2).

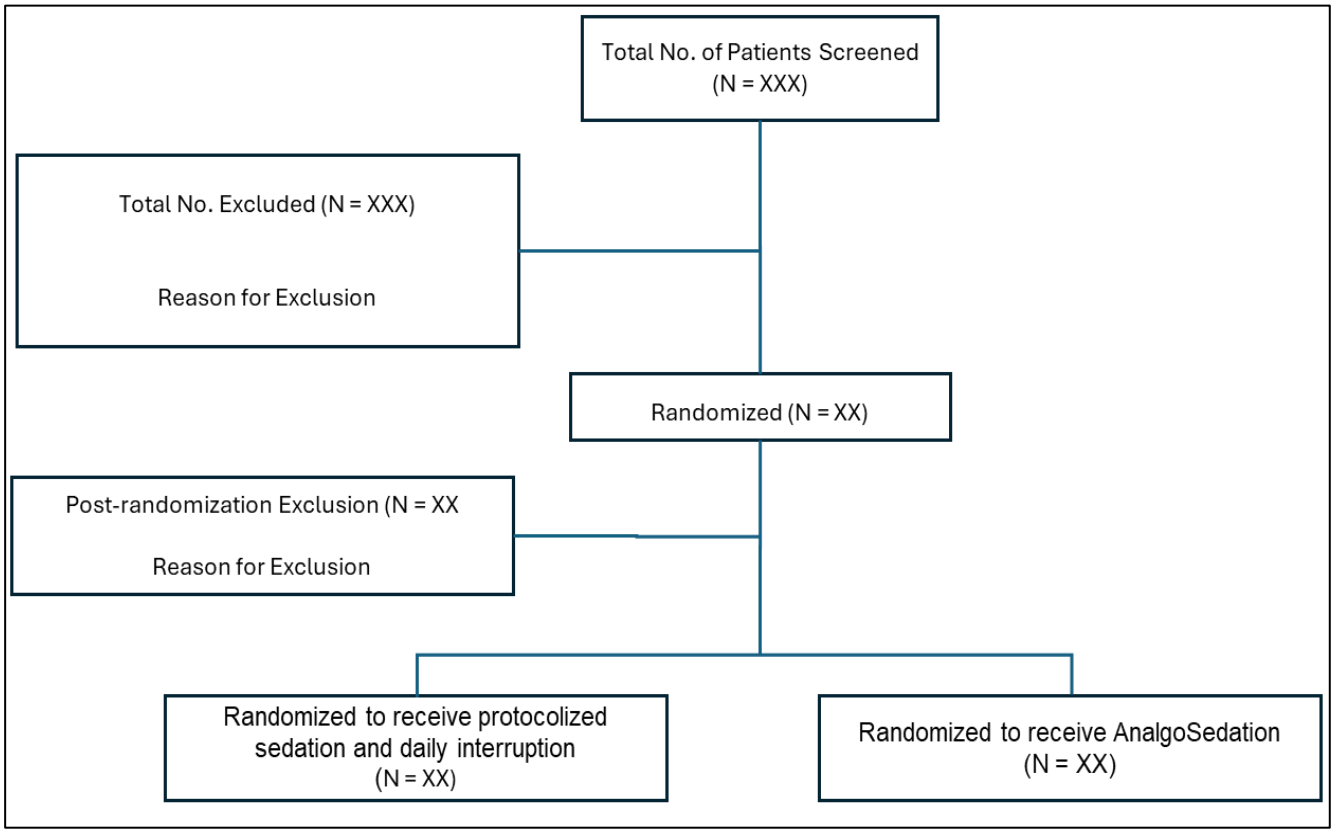

Figure 1: Flow of patient enrollment and randomization in the trial.

	Enrolment	Allocation				
TIMEPOINT**	**$-t_1$**	**0**	**t_1**	**t_2**	**t_3**	**t_4**
ENROLMENT:						
Eligibility screen	X					
Informed consent	NA					
Allocation		X				
INTERVENTIONS:						
Analgosedation			◆	——— ◆		
PDS+SAT (control)			X	X		
ASSESSMENTS:						
Baseline Variables	X					
Primary Outcome *VFD-10*	X			X		
Secondary Outcomes *Time to extubation; Total sedative; ICU LOS*	X			X	X	
Secondary Outcomes *DCFDs; Hospital LOS; disposition after discharge*	X					X

Figure 2: Schematic of participant timeline in the trial.

*Ventilator-Free-days over 10 days (VFD-10), Duration of mechanical ventilation, duration of weaning, total sedatives and analgesics, days in the ICU and hospital, delirium-coma-free days (DCFDs) **t_1. initiation of sedation strategy; t_2 date of successful extubation. t_3 date of transfer out of the intensive care unit; t_4 date and status of hospital discharge.

Fidelity, feasibility, and nursing acceptance

A prior pilot RCT found use of a similar analgosedation (SAT) protocol in non-trauma ICU adults, had strong fidelity, was feasible for ICU clinicians to use administer, and had high nursing acceptance.[5,6] The feasibility of conducting PC-RCTs in ICU has been demonstrated.[30]

Participants/setting

Adults with trauma admitted to a 44-bed ICU at a 420-bed trauma center, receiving continuous sedatives/ analgesics who are expected to require IMV ≥48 hours.

Eligibility criteria

Eligible patients include those: admitted to both to ICU and trauma service; age ≥18 years; receiving IMV; and receiving continuous sedative and/or analgesic infusion.

Exclusion criteria

Exclusion criteria excluded-presence of a profound neurologic deficit (e.g., intracranial injury) or GCS ≤6; brain death or expected brain death; receiving a SBT with extubation anticipated in the next 24 hours; presence of a tracheostomy; use of sedative infusions for seizures or acute substance withdrawal; treatment for opioid use disorder before admission; use of scheduled neuromuscular blockers; moribund, with treatment limitations, or who are unlikely to be weaned from IMV, enrollment in a confounding study, use of continuous sedatives and/or analgesics >24 hours before presentation to study hospital and allergy to an opioid, midazolam, lorazepam, dexmedetomidine, or propofol.

Consent process

MemorialCare LBMC IRB approved protocol with waiver of informed consent (IRB MHS project no. 279.22) given that eligible patients will not be able to provide their own consent (critically ill, intubated, and receiving sedatives) and legally authorized representatives to trauma ICU patients are often not present/ available. Trial registered at www.ClinicalTrials.gov before start of study enrollment (NCT05751863).

Study interventions

Study interventions were shown in the Figure 1.

Explanation for the choice of comparators

The intervention group includes IMV trauma patients managed with an analgosedation (+SAT) protocol. The

control group includes IMV trauma patients managed with a traditional sedation (PDS+SAT) protocol. Clinical equipoise exists between the use of these two protocols among trauma surgeons/intensivists.

After discussion between admitting physician and PI, patients will be allowed to cross over to the other protocol if the admitting physician deems it absolutely necessary.

Usual care arm: PDS+SAT sedation protocol

During the months the ICU is randomized to use of the traditional sedation (PDS+SAT) protocol, this protocol will be used for all the patients meeting study criteria.

Protocol and procedure

Nurses will titrate analgesic and sedative infusions according to the institutional PDS+SAT protocol (Figures 3 A and B). The Richmond agitation sedation scale (RASS) will be used to evaluate level of sedation; sedative infusions will be titrated to maintain light sedation (i.e., a RASS=0 to -2). The critical-care pain observation tool (CPOT) will be used to evaluate pain; analgesics will be titrated to maintain a CPOT ≤2.[1] While the preferred sedative for trauma patients is propofol; since midazolam and dexmedetomidine are also included in the institutional ICU sedation protocol, their use (following protocol criteria) will be at discretion of clinicians.[31]

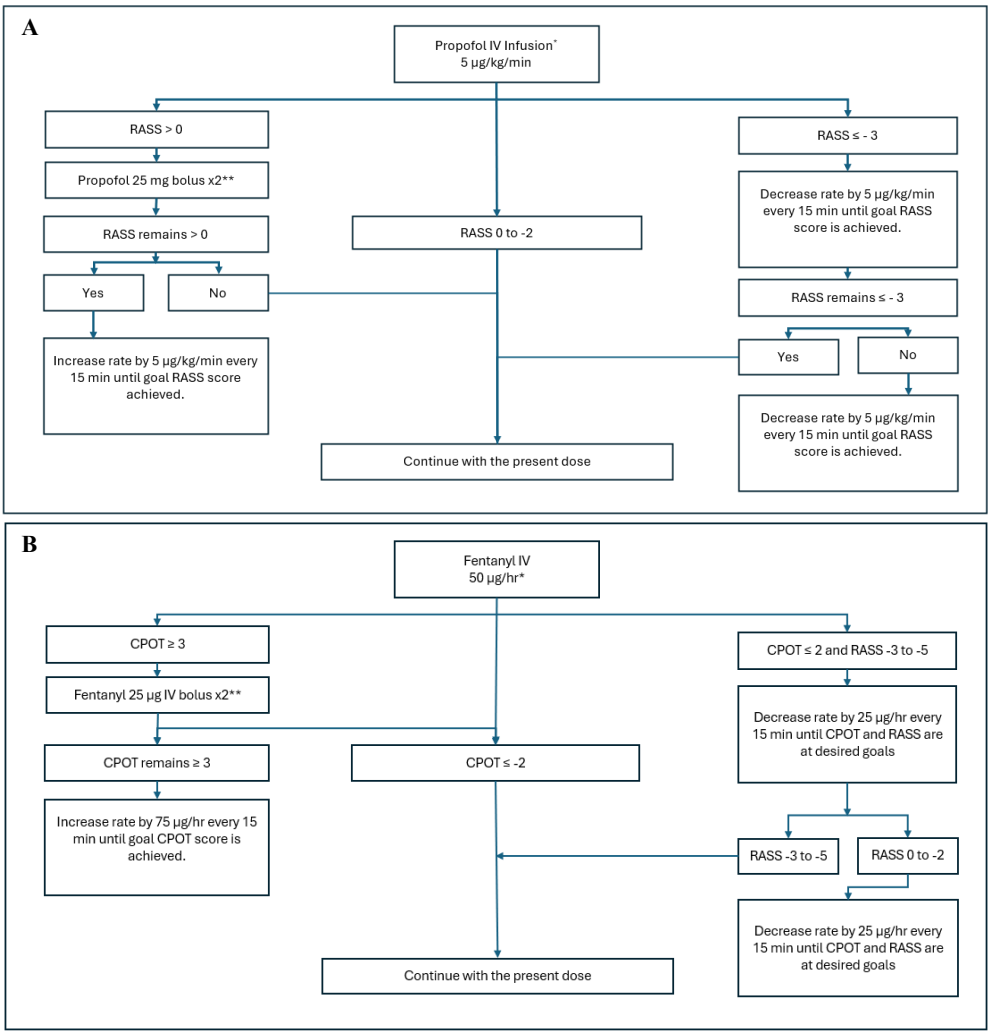

Figure 3: (A)PDS + SAT protocol agitation and anxiety management with propofol and (B) PDS + SAT protocol for pain management with fentanyl.

A-*The maximum propofol infusion dose is 50 mcg/kg/min. Nurses are to notify the Intensivist if the maximum dose is reached. **To treat agitation, two doses of 25 mg of IV propofol every 5 minutes are required before increasing the continuous infusion rate. After initiating propofol, the following tests are ordered and repeated in 72 hours: amylase, lipase, and triglyceride. Discuss CPOT goal and RASS goal scores daily with the intensivist and update them according to the patient's clinical progress.

B-*The maximum dose of the propofol infusion is 10 µg/kg/min up to 600 µg/hr. **Two doses of 25µg of IV fentanyl, given every 5 minutes, are required to treat pain before increasing the continuous infusion rate. Nurses are to notify the Intensivist if the maximum dose is reached. Discuss CPOT goal and RASS goal scores daily with the Intensivist and update according to patient's clinical progress.

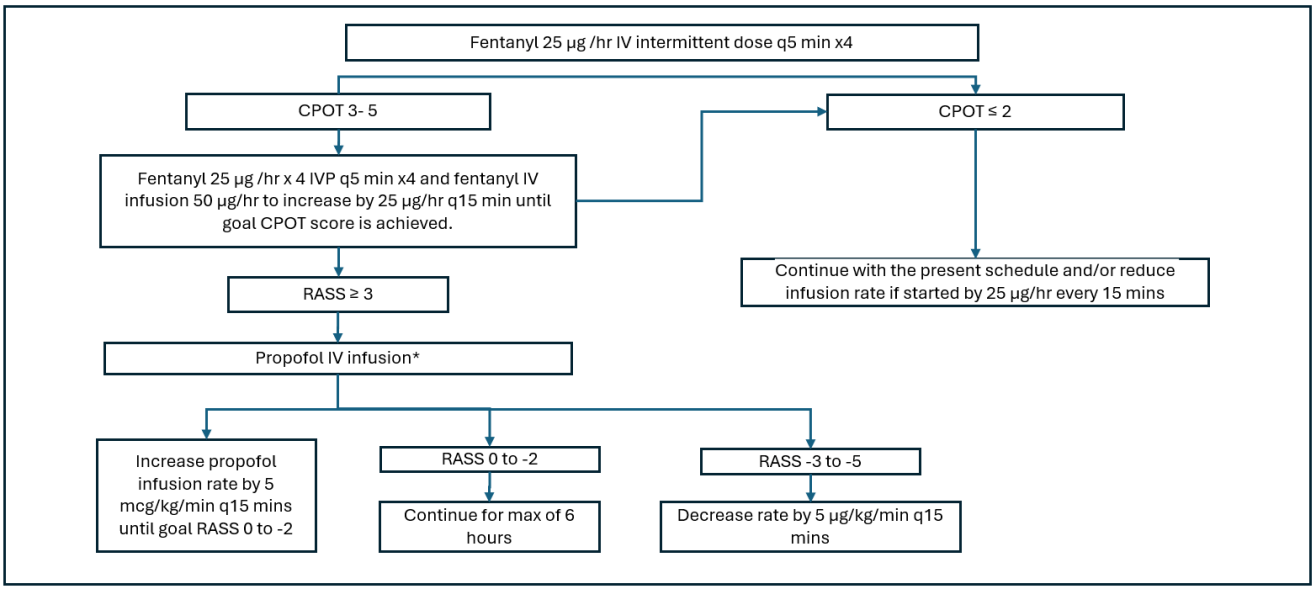

Figure 4: Anagosedation protocol.

*Propofol infusion starts at 5 µg/kg/min and titrates by 5 µg/kg/min every 15 min until the goal RASS score is achieved. The maximum duration of propofol IV infusion is 6 hours, and the maximum dose is 10 µg/kg/min up to 600 µg/hr. Discuss CPOT goal and RASS goal scores daily with the Intensivist and update them according to the patient's clinical progress.

SAT procedure

A SAT screen will occur every morning unless ≥1 exclusion criterion is present. When SAT screen is passed, bedside nurse will interrupt all sedatives and opioids and evaluate patient hourly until wakefulness (RASS=0) is reached. Patient will be deemed to have passed the SAT if they remain comfortable; SAT failure defined as presence of agitation (RASS≥2) accompanied by presence of discomfort, anxiety, and/or diaphoresis. In this instance, sedative (or opioid) infusion will be restarted at 50% of prior rate. Any reason for protocol non-compliance will be documented. Additionally, any interruption of benzodiazepine and opioid infusions in analgosedation patients will be recorded.

Intervention to be evaluated

Analgosedation

During the months the ICU is randomized to the analgosedation (+SAT) protocol, trauma patients meeting all study criteria will be managed with the analgosedation (+SAT) protocol.

Protocol and procedure

The goal of the analgosedation protocol is to maintain patients at a state of mild pain (i.e., CPOT ≤2) and light sedation (i.e., RASS=0 to -2) using analgesics, primarily fentanyl, rather than non-analgesic sedatives. Intermittent analgesic(s) (vs continuous infusions) will initially be used to reach the pain goal where patients with a CPOT ≥3 or a RASS ≥1 will be treated with intravenous bolus doses of fentanyl 25 µg every 5 minutes, up to four doses, until both mild pain and light sedation are achieved. If the pain and sedation goals cannot be reached with intermittent fentanyl therapy, a fentanyl infusion at 50 mcg/hr will be initiated and titrated upwards every hour by 50 mcg/hr for up to two times for a CPOT ≥3 or a RASS ≥1. Each fentanyl infusion increase will be accompanied by a single fentanyl bolus of 50 mcg. If a CPOT ≥3 or a RASS ≥1 still exists the fentanyl infusion will be continued, and a propofol infusion will be initiated at five mcg/kg/min and titrated by five mcg/kg/min every 15 minutes for up to 6 hours until a RASS of 0 to -2 is reached (Figure 4).

Criteria for discontinuing or modifying allocated interventions

The beside clinician will continuously monitor patients for the presence of an anticipated adverse effects, and after consultation with the study team, terminate or modify use of the analgosedation (or tradition sedation) protocol.

Minimizing confounders

Efforts to minimize potential study confounders are important to optimize in an unblinded study like the one being proposed. Co-interventions, including use of a multimodal pain management approach (i.e., use of non-opioid analgesics to optimize pain control and reduce opioid exposure) and an IMV SAT-SBT protocol, are well-established in study ICU, and compliance with their use will be evaluated. Data on other ICU care elements with the potential to influence a study outcome (e.g., bedside procedures, the arterial partial pressure of oxygen

(P_aO_2): inspired oxygen concentration (FiO_2) ratio, and use of neuromuscular blockers will be collected.

Strategies to improve adherence to interventions

Study compliance will be maintained through both didactic and bedside clinician training sessions, development of a standard operating procedure (SOP) manual, study protocol reviews and training by coordinators, a 24/7 helpline, daily reminders from coordinators, and routine compliance audits.

Evidence-based, concomitant care will be permitted

Multimodal pain management

This is a guideline-recommended approach to optimize pain control and reduce opioid use (through the use of NSAIDs, muscle relaxants, gabapentin/pregabalin, and acetaminophen) in surgically critically ill adults and will therefore be allowed in all trial participants.[1]

Standardized weaning protocol

This is a guideline-recommended approach to facilitate the liberation of patients from IMV. This protocol consists of a daily SAT (see above) followed by an SBT. For patients meeting the SBT safety screen [adequate oxygenation (SpO_2 ≥90% on a F_IO_2 ≤40%, PEEP ≤5 cm H_2O), no recent myocardial ischemia, hemodynamic stability, and no increased intracranial pressure], they will be placed on CPAP 5 cm H_2O and pressure support 6 cm H_2O for up to 120 min. Over the course of the SBT the RN and RCP will monitor for the presence of SBT failure criteria [any one of the following: respiratory rate >35 or <8 for ≥5 min, an SpO_2 <88% for ≥5 min, a mental status change/cardiac dysrhythmia; any 2 of following: a heart rate >130 or <60 bpm, accessory muscle use, abdominal paradox, diaphoresis/dyspnea]. The presence of this SBT failure criteria will result in patient being placed on their prior IMV settings. Successful SBT prompts notification to primary physician to make an extubation decision.

A nurse-driven early mobility protocol

An early mobilization protocol has already been implemented in the study ICU, and all patients will be screened and considered for participation each day.

Delirium assessment and reduction

Twice daily delirium screening with the confusion assessment method (CAM) for the ICU, and delirium risk factor reduction when a patient screens positive, is a well-established part of nursing care in the study ICU.[32] Guideline-recommended delirium treatment with antipsychotics in patients with delirium-associated symptoms may be used at the ICU team's discretion.

Outcome measures

Primary outcome measures

Ventilator-free days (VFDs) during the first 10 days of IMV (VFD-10). This outcome is preferred in ICU trials evaluating duration of IMV (over the actual duration of mechanical ventilation) given it accounts for patients who require reintubation after a failed extubation, who die in the ICU before extubation, or patients who require a prolonged duration of IMV.[25,33] These considerations are important in the trauma ICU population who typically have either a short/very long duration of IMV (Table 1).[34]

Table 1: Patient outcomes.

Variables	PDS+SAT	Analgosedation	Measure of effect (95% CI)	P value
Ventilator-free days (VFDs) over 10 days (VFD-10)				
Days to successful extubation, median, (IQR)				
Days in ICU, median (IQR)				
ICU mortality, N (%)				
Hospital mortality, N (%)				
Reintubation within 48 h, N (%)				
Delirium, N (%)				
Day without delirium or coma, N (%)				
Reintubation within 48 h, N (%)				
Tracheostomy, N (%)				
Vasopressors/inotropes, N (%)				
Unintentional device removal, N (%)				
Endotracheal tube				
Gastric tube				
Urinary catheter				
Central venous or arterial catheter				
Surgical drains				

Secondary outcome measures

Duration of IMV weaning

The time from the start of IMV weaning (i.e., the first SBT) to successful extubation.

Delirium- and coma-free days (DCFDs)

Days alive without delirium (assessed by CAM-ICU) or coma (RASS score -4 or -5) during the first 14 days after ICU admission (or until death occurs). Total ICU daily analgesic (IV morphine MEQ) and sedative exposure (IV midazolam MEQ).

Extubation failure

Requiring reintubation within 48 hours. ICU and hospital length of stay (until discharge or death). Death occurring within 28 days of enrollment. Inadvertent removal of the endotracheal tube.

Participant timeline

Patients will continue to receive standard care throughout their hospitalization, but all study interventions will cease 14 days regardless of whether the patient remains in the ICU. Participants will be monitored, and outcome data will be collected until 1) hospital discharge, 2) death, or 3) transfer to an outside facility. No post-hospital discharge follow-up is planned (Figures 1 and 2). The estimated overall duration of the clinical trial is 24 months.

Sample size

A sensitivity analysis was used to determine the minimum detectable difference in VFD-10 days between the two groups by varying assumptions around the VFD-10 outcome. Using a standard deviation (σ) between 4.0 and 8.0 based on the distributions for VFD-10 days reported in major ICU trials, a two-sided alpha of 0.05, 80% power and a SD of 6.0 days, we calculated a sample of 170 patients (85 per protocol arm), would be powered to detect a 1.5-day difference in VFD-10. This design is consistent with contemporary sedation trial methodology, balancing clinical relevance and feasibility.[33,34]

No additional inflation for attrition or clustering is applied, as this trial is designed for pragmatic implementation with complete follow-up through hospital discharge.

Recruitment and randomization scheme for intervention assignment

The 24-month trial will employ an unblinded, PC-RCT, multiple-crossover design, where data on the use of the analgosedation (+SAT) protocol for 12 months will be compared to data on the use of the traditional sedation (PDS+SAT) protocol for 12 months in adult IMV trauma patients. After implementation and training, the analgosedation protocol will be used for the first month of the study.

During this period, the analgosedation protocol will be revised, as required, based on investigator observation and clinician feedback.

Thereafter, on each of the subsequent 23 months, the study ICU will be randomly assigned to use either the analgosedation (+SAT) protocol or the sedation (+PDS/SAT) protocol, resulting in each protocol being used for a total of 12 months.

Data collection

Data collection will include patient demographics, trauma-specific frailty score, extubation outcome, weaning duration, ICU and hospital stay, mortality, drug use, adverse events, delirium, ventilation duration, extubation failure, and self-extubation (Table 2).

Table 2: Baseline characteristics.

Characteristics	PDS+SAT	Analgosedation
Age, (in years), median [IQR]		
Male sex, N (%)		
Race (%)		
Trauma frailty index, mean [±SD)		
Admitting diagnosis, N (%)		
APACHE II score, median (IQR)		
SOFA at day 1, median (IQR)		
Mechanical ventilation, median (IQR)		
Opioid infusion		
N (%)		
Days of infusion, median (IQR)		
Sedative infusion		
No. (%)		

Continued.

Characteristics	PDS+SAT	Analgosedation
Days of infusion, median (IQR)		
Co-morbid diagnosis, N (%)		
COPD		
Sepsis		
Cardiac failure		
Alcohol use		
Renal dysfunction		
Any neurological condition		
Any psychiatric condition		
Post operative respiratory failure		
Hepatic dysfunction		

Data management and confidentiality

All patient-identifiable information will be kept confidential during and after the research. The study involves collecting existing data, so patients cannot be directly identified; only study IDs will be used, created with secure keys. Data is accessible only to investigators, stored securely, and collected by trained assessors with duplicate measurements for accuracy. The primary data source is electronic medical records, which are de-identified. Data will be coded with non-identifiable keys and stored separately from personal information. Data will be stored in a password-protected file and kept separate from other identifiable participant information. All data will be maintained in a locked cabinet with restricted access to research team members. Research data will be anonymous. Data will be retained for five years; afterward, electronic data will be permanently deleted, and written copies will be destroyed.

Statistical analysis plan

All analyses will be performed using an intention-to-treat (ITT) approach, in which all enrolled patients are analyzed according to their assigned group, regardless of adherence to the protocol. This method ensures the preservation of the benefits of randomization and reflects real-world effectiveness. Baseline characteristics will be summarized using descriptive statistics (Table 2). Continuous variables will be reported as means with standard deviations or medians with interquartile ranges, depending on distribution. Between-group comparisons for continuous variables will utilize Student's t-test (with Welch's correction if variances are unequal) or the Mann-Whitney U test as appropriate. Categorical variables will be expressed as frequencies and percentages, with comparisons conducted using Pearson's chi-squared test or Fisher's exact test when expected cell counts are small.

Primary analysis

The primary outcome**,** VFD-10**,** will be analyzed using Kaplan-Meier survival analysis with censoring for death, transfer, or study withdrawal. Differences between the intervention and control arms will be assessed using the log-rank test. To account for competing risks (e.g., death before extubation), cumulative incidence functions will be constructed, and cause-specific hazard ratios (HRs) with 95% CIs will be estimated using Cox proportional hazards models. In addition, a time-dependent Cox regression model will be constructed to account for daily ICU-level variables that may influence extubation, including sedation level (RASS), pain score (CPOT), delirium status (CAM-ICU), oxygenation (PaO_2/FiO_2 ratio) and cumulative daily opioid and sedative doses. This approach will help isolate effect of sedation strategy from time-varying clinical factors.

Secondary analyses

Secondary outcomes (e.g., duration of IMV weaning, delirium- and coma-free days, drug exposure, ICU/hospital length of stay, self-extubation, and mortality) will be analyzed using generalized linear models. Binary outcomes will be reported as odds ratios (ORs) with 95% CIs, continuous outcomes as mean or median differences with corresponding CIs, and time-to-event outcomes with HRs as appropriate.

Handling missing data and protocol non-adherence

Due to pragmatic design, integration with electronic medical records, and regular study team engagement, missing data are expected to be minimal. When data are missing, last observation carried forward (LOCF) method will be applied, consistent with prior ICU trials. Sensitivity analyses will explore impact of missingness. No interim analysis is planned.

Oversight and monitoring

The IRB did not request a DSMC, as both strategies are guideline-recommended approaches for ICU sedation.[1] The principal investigator will inform relevant parties of any important protocol changes (e.g., investigators, REC/IRBs, participants, registries, journals, regulators).

Safety

The ICU staff will document all unplanned extubations and any other noteworthy clinical events (AE and SAE) to the study team for further safety evaluation.

Serious adverse event reporting and harms

The principal investigator or managing ICU physician will determine whether a serious adverse event (SAE) is related to the study. All such AE and SAEs will be reported to the IRB within 72 hours.

Dissemination plans

We plan to publish the study findings in peer-reviewed academic journals. We also intend to present this study at local, national, and international conferences.

Patient and public involvement

Patients and the public were not involved in the design of this study. Patients and the public will be informed of the study results via peer-reviewed journals or academic conferences.

DISCUSSION

Sedatives and analgesics requirements differ between ICU patients admitted with trauma and those who are not.[17,35] In critically ill trauma patients, the goal is to reduce pain, anxiety, and agitation, notably after surgery. Trauma providers often avoid SAT, particularly in patients where agitation may compromise surgical success (e.g., a patient with an open abdomen).[17,35] Limited published guidance exists on the best sedation strategy for trauma patients, highlighting the need for further research.[21,25] While pain-focused sedative approaches, including analgosedation, seem to be well-suited to critically ill trauma patients, this strategy has only been rigorously studied in medical and general surgical ICU adults.[1,36-38]

The observational studies that have investigated pain and sedative approaches in critically ill trauma patients remain limited.[39-42] Russo et al conducted an observational study in 262 severe traumatic brain injury (TBI) patients. They found that propofol was the most common sedative, but did not use propofol to influence any relevant outcome, including 60-day mortality.[31] While a systematic review of four trauma-specific sedation ICU studies comparing propofol and midazolam found efficacy and safety to be similar, these studies primarily focused on long-term safety rather than patient-centric outcomes.[43] Similarly, a review of 13 ICU sedation RCTs noted that a lack of outcome data existed in ICU patients with trauma.[44] The goal of our investigation is to better understand how the choice of sedation strategies impacts key outcomes in ICU patients admitted with trauma.

While one landmark RCT studied an analgesia-first approach in critically ill, mechanically ventilated patients and found that the analgosedation strategy was associated with more than four more ventilator-free days (13.8 vs. 9.6; p=0.019) and shorter ICU and hospital stays, the trial excluded patients with trauma.[22] Our search (1966-Nov 2023) in MEDLINE and clinicaltrials.gov found no prospective trials on analgosedation in trauma patients. The best sedation strategy for critically ill trauma patients remains unknown, and our pragmatic, cluster RCT aims to rigorously evaluate the role of analgosedation in this population.

Traditional, exploratory ICU trials often suffer from low external validity: consent is usually required from the legally authorized representative, which is often obtained routinely. Outcome assessment is typically labor-intensive, needing trained evaluators. The high external validity of pragmatic trials stems from their conduct in regular clinical settings, the enrollment of a diverse population (due to few exclusions), the use of a waiver of informed consent, and clinicians (rather than researchers) delivering the intervention in a routine manner.[45,46] The results of our planned study will provide insights into preferred sedation practices during mechanical ventilation. This research will also promote a multidisciplinary approach to managing patients on IMV. The study's objectives are clinically relevant and will encourage further research aimed at improving patient outcomes, especially in mechanically ventilated trauma patients. Additionally, there is potential for economic benefits if ICU and/or hospital stay duration is shortened.

CONCLUSION

Findings from this trial will inform sedation practices in trauma ICU patients by evaluating the impact of an analgosedation protocol on ventilator-free days and other key outcomes.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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