Hacettepe University Faculty of Medicine
Department of Anesthesiology and Reanimation

Clinical Trial Study Protocol

Official Title: Comparison of Eleveld and Schnider Target-Controlled Infusion (TCI) Models for Propofol Sedation in Intensive Care Unit Patients

NCT Number: NCT PENDİNG

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Background and Rationale

Evidence-based international guidelines on ICU sedation for mechanically ventilated patients provide similar recommendations. Sedation is routinely administered in critically ill patients to reduce anxiety, facilitate procedures, decrease oxygen consumption and autonomic hyperactivity, and minimize ventilator asynchrony. The goal is to maintain patient comfort and hemodynamic stability while ensuring easy arousability, except in cases requiring deep sedation. Current guidelines recommend using the minimum effective sedation level and performing daily awakening to improve outcomes. Propofol is the preferred sedative due to its rapid onset and predictable recovery. Target-Controlled Infusion (TCI) systems help achieve desired effect-site concentrations based on pharmacokinetic and pharmacodynamic models. The Schnider model is widely used, while the newer Eleveld model integrates broader demographic covariates and has superior predictive performance. This study compares both models in ICU sedation regarding hemodynamic stability, sedation performance, awakening, extubation, ICU discharge, and delirium incidence.

Study Objectives

To compare the clinical performance of the Eleveld and Schnider propofol TCI models in ICU patients regarding hemodynamic stability, sedation performance, awakening and extubation times, delirium incidence, and ICU length of stay.

Study Design

Study Type: Observational (Prospective Cohort Study)
Time Perspective: Prospective
Study Location: Hacettepe University Faculty of Medicine, Department of Anesthesiology and Reanimation, Intensive Care Unit, Ankara, Türkiye
Study Period: February 2025 – December 2025
Estimated Enrollment: 84 participants (42 per group)
Sampling Method: Consecutive sampling

Two groups will be observed:
1. Patients sedated with propofol using the Schnider TCI model.
2. Patients sedated with propofol using the Eleveld TCI model.

Sedation with TCI propofol is routine practice in the ICU, and this study will not alter clinical management or drug choice. The responsible anesthesiologist will decide on sedation use independently.

Eligibility Criteria

Inclusion Criteria:
- Age ≥18 years
- ASA I–IV
- Sedation required for mechanical ventilation

- Sedation ≤72 hours
- Informed consent obtained

Exclusion Criteria:
- ASA >IV
- BMI ≥35
- Propofol allergy or lipid metabolism disorder
- Sedation >72 hours
- Neurological or neurodegenerative disease affecting consciousness assessment

Outcome Measures

Primary Outcome:
- Sedation depth accuracy (BIS 40–60, Riker SAS 3–4)

Secondary Outcomes:
1. Hemodynamic stability (MAP, HR)
2. Awakening and extubation times
3. Delirium incidence (CAM-ICU)
4. ICU length of stay
5. Adverse events

Data Collection and Analysis

Demographic and clinical data (age, sex, height, weight, comorbidities) will be recorded. Sedation depth will be evaluated every 4 hours using BIS and Riker SAS. Statistical tests: Shapiro–Wilk for normality; Student's t-test or Mann–Whitney U for continuous variables; Chi-square or Fisher's exact test for categorical variables; significance set at $p<0.05$.

Ethical Considerations

Approved by the Hacettepe University Clinical Research Ethics Committee. Written informed consent will be obtained. No deviation from standard ICU practice will occur. The study is purely observational.

Research Team

Principal Investigator: Assoc. Prof. Başak Akça
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