

The Impact of Frailty and Different Sedation Techniques on Cognitive Function in Geriatric Colonoscopy Patients

NCT Number: 07384169
Document Type: Study Protocol
Ethics Committee Approval Date: 19 July 2023

Brief Description

This prospective, observational study evaluates the impact of frailty status and different sedation techniques on postoperative cognitive function in geriatric patients undergoing elective colonoscopy. Cognitive changes are assessed using the Mini-Mental State Examination (MMSE) at predefined time points.

Study Design

Study Type: Observational

Study Design: Prospective cohort study

Allocation: Non-randomized

Study Setting: Single-center endoscopy unit

Participants

Inclusion Criteria: Age \geq 65 years, elective colonoscopy, ASA physical status I–III, provision of written informed consent

Exclusion Criteria: Second- or third-degree atrioventricular (AV) block, a recent history of strokes, severe hypotension, cardiorespiratory instability, substance abuse or psychotic illness, severe dementia, emergency colonoscopy. Development of major procedural or anesthetic complications (bleeding, perforation, respiratory arrest, or cardiac arrest

Frailty Assessment

Frailty status is assessed preoperatively using the FRAIL scale, and patients are categorized according to frailty classification

Sedation Management

The choice of sedative agent is made by the attending anesthesiologist based on clinical judgment.

Propofol group: Loading dose of 0.2–0.5 mg/kg IV followed by intermittent bolus dosing as required

Dexmedetomidine group: Loading dose of 0.5 μ g/kg IV administered over 10 minutes

All patients receive fentanyl 0.5 μ g/kg IV. Sedation depth is maintained at a Ramsay Sedation Score of 3–4.

Outcome Measures

Primary Outcome: Change in cognitive function assessed by Mini Mental State Examination scores

Time Frame: baseline (pre-procedure), 2 hours post-procedure, and 24 hours post-procedure Mini Mental State Examination scores can be between 0-30. >10 severe impairment, 10-19 moderate dementia 19-24 early dementia 25 \leq normal

Secondary Outcomes: Frailty was assessed using the Clinical Frailty Scale prior to colonoscopy.

Time Frame: baseline (pre-procedure) Frail scores can be between 0-5. 0 normal, 1-2 Pre-frail, 3-5 Frail

Statistical Analysis

Continuous variables are assessed for normality using appropriate methods. Data are summarized as mean \pm standard deviation or median (minimum–maximum). Between-group comparisons are performed using parametric or non-parametric tests as appropriate. Repeated measurements are analyzed using Friedman's test with Bonferroni correction for multiple comparisons. Statistical significance is set at $p < 0.05$.

Ethical Considerations

The study is conducted in accordance with the Declaration of Helsinki and was approved by the local Ethics Committee. Written informed consent is obtained from all participants prior to enrollment.