**STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN (SAP)**

# Comparison of the Efficacy of Nasal Mask and Nasal Cannula Oxygenation During Gastrointestinal Endoscopic Procedures Performed Under Target-Controlled Propofol Infusion Anesthesia With SedLine Brain Function Monitoring: A Randomized Controlled Trial

*Impact of Nasal Mask Versus Nasal Cannula Oxygenation on Hypoxemia in Gastrointestinal Endoscopy: A SedLine-Guided Randomized Controlled Trial*

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Issuing Organization: SBÜ Sancaktepe Şehit Prof. Dr. İlhan Varank Training and Research Hospital Scientific Research Ethics Committee

Facility: University of Health Sciences Sultan Abdulhamid Han Training and Research Hospital, Istanbul, Turkey

Ethics approval: Approval No. 2024/392 (December 26, 2024)

Study Start Date: January 06, 2025 (Actual)
Primary Completion Date: August 26, 2025 (Actual)
Study Completion Date: November 15, 2025 (Actual)
Overall Recruitment Status: Completed
Enrollment: 600 participants (Actual)

Document Date: December 15, 2025

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## 1. Study Synopsis

Design: Prospective, randomized, parallel-group, open-label controlled trial.
Population: Adults (18–75 years), ASA physical status I–III, scheduled for gastroscopy and colonoscopy in the same session.
Interventions: Oxygen at 4 L/min via a nasal mask versus standard nasal cannula during target-controlled propofol sedation.
Sedation monitoring: SedLine® brain function monitoring with Patient State Index (PSI) targeted between 50 and 80.
Primary outcome: Hypoxemia incidence ($SpO_2 \leq 90\%$).
Sample size: 600 participants (300 per group).

## 2. Background and Rationale

Hypoxemia is a common and clinically important adverse event during propofol-sedated gastrointestinal endoscopy. Standard nasal cannula oxygen supplementation may be insufficient in some patients. A nasal mask can improve oxygen delivery and potentially reduce hypoxemia and airway interventions. This trial evaluates whether a nasal mask reduces hypoxemia compared with a standard nasal cannula under a standardized, SedLine-guided, target-controlled infusion (TCI) propofol sedation protocol.

## 3. Objectives

Primary objective: To compare the incidence of hypoxemia ($SpO_2 \leq 90\%$) between the nasal mask and nasal cannula groups during the procedure.

Secondary objectives: To compare severe hypoxemia, hypoxemia duration, minimum $SpO_2$, need for airway interventions, procedure time, recovery time, adverse events, and clinician satisfaction scores.

## 4. Study Design

This is a single-center, interventional, randomized (1:1), parallel-assignment trial. Blinding was not feasible due to the visible oxygen delivery device.

## 5. Study Population

### 5.1 Inclusion Criteria

- Age 18–75 years
- ASA physical status I–III
- Scheduled to undergo both gastroscopy and colonoscopy in the same session
- Planned intravenous propofol sedation for the procedure

### 5.2 Exclusion Criteria

- Myocardial infarction within 6 months or unstable angina history
- Severe arrhythmia history
- Acute pharyngitis, tonsillitis, or pneumonia
- Baseline room air $SpO_2 \leq 90\%$
- Severe cardiopulmonary disease or anticipated difficult airway
- Severe obstructive sleep apnea syndrome
- Known allergy to propofol, egg, soy, albumin, lidocaine, or similar agents
- Pregnancy or lactation
- Participation in another clinical study within the previous 3 months
- Inability to provide informed consent

## 6. Randomization and Allocation

Participants were randomized 1:1 to nasal mask versus nasal cannula oxygenation using a pre-prepared randomization list. Allocation was implemented using opaque, sealed envelopes.

## 7. Interventions and Procedures

### 7.1 Oxygenation

Nasal mask arm: Oxygen at 4 L/min delivered via a nasal mask covering the nasal area.
Nasal cannula arm: Oxygen at 4 L/min delivered via a standard adult nasal cannula.

### 7.2 Sedation Protocol

All participants received propofol sedation using a target-controlled infusion system. Sedation was titrated to maintain SedLine PSI values between 50 and 80. Standard monitoring included noninvasive blood pressure, ECG, heart rate, and peripheral oxygen saturation ($SpO_2$).

## 8. Outcome Measures

### 8.1 Primary Outcome

Incidence of hypoxemia during the procedure, defined as any occurrence of $SpO_2 \leq 90\%$.

### 8.2 Secondary Outcomes

- Severe hypoxemia: $SpO_2 \leq 75\%$ or $SpO_2 \leq 90\%$ for >60 seconds
- Duration of hypoxemia (seconds)
- Minimum $SpO_2$ during the procedure
- Need for airway interventions
- Adverse events

- Procedure time and recovery time
- Clinician satisfaction scores (0–100)

## 9. Statistical Analysis Plan

All analyses were performed in the intention-to-treat population using IBM SPSS Statistics (version 26.0). Sample size calculations were performed using PASS (version 11.0). Two sided $p < 0.05$ was considered statistically significant unless otherwise specified.

Normality was assessed using the Shapiro–Wilk test. Continuous variables were compared using the independent samples t test or Mann–Whitney U test, as appropriate, and are reported as mean ± standard deviation or median [interquartile range]. Hodges–Lehmann median differences with 95% confidence intervals were calculated for selected non normally distributed continuous outcomes. Categorical variables were compared using chi square or Fisher's exact tests, and key binary outcomes were reported with relative risk and odds ratio with 95% confidence intervals.

Baseline balance was assessed using absolute standardized difference ($|ASD| < 0.10$). Spearman correlation was used for associations between continuous variables. PSI was defined as the mean between 5 and 20 minutes after induction (PSI 5–20). Exploratory minute based logistic regression at 5, 10, 15, and 20 minutes used Bonferroni correction ($p < 0.0125$). Subgroup analyses (age, sex, BMI, ASA) used treatment-by-subgroup interaction terms (Wald test) with Bonferroni corrected threshold $p < 0.0125$ for interaction testing. Multivariable logistic regression was used to identify predictors of hypoxemia.

## 10. Ethics and Dissemination

The study was approved by the local ethics committee and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants.

## 11. Version History

Version: 1.0

Date: December 15, 2025

Summary of changes: Initial version prepared for ClinicalTrials.gov PRS Study Documents upload.