

# High-flow oxygen compared with standard oxygen to prevent low oxygen levels during sedated gastrointestinal endoscopy

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/03/2026	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/03/2026	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

During gastrointestinal endoscopy performed under sedation, patients may develop low oxygen levels due to the effects of sedative drugs on breathing. Standard oxygen therapy delivered through a nasal cannula may not always be sufficient to prevent this. High-flow oxygen therapy delivers warmed and humidified oxygen at higher flow rates and may improve oxygen levels. The aim of this study is to compare high-flow oxygen with standard oxygen therapy in preventing low oxygen levels during sedated endoscopy.

### Who can participate?

Adults aged 18 years or older undergoing planned gastrointestinal endoscopy under sedation in a hospital setting.

### What does the study involve?

Participants receive oxygen therapy during their endoscopic procedure as part of routine care. Depending on the attending anesthesiologist's decision, patients receive either standard oxygen through a nasal cannula or high-flow oxygen therapy. Vital signs, including oxygen levels, heart rate, and blood pressure, are monitored continuously during the procedure. The study records any episodes of low oxygen levels and any interventions required to support breathing.

### What are the possible benefits and risks of participating?

Participants may benefit from improved monitoring and oxygen support during the procedure. There are no additional risks beyond standard clinical care, as both oxygen delivery methods are routinely used in clinical practice.

### Where is the study run from?

The study is conducted at University Hospital "N. I. Pirogov", Sofia, Bulgaria.

### When is the study starting and how long is it expected to run for?

The study starts in March 2025 and runs until August 2025.

Who is funding the study?  
Investigator initiated and funded.

Who is the main contact?  
Mina Vapireva, MD  
mvapireva@gmail.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

## Study information

### Scientific Title

Adult patients undergoing sedated gastrointestinal endoscopy receiving high-flow nasal oxygen compared with low-flow nasal oxygen for the prevention of hypoxemia: a prospective observational study

### Acronym

HFNO-ENDO

### Study objectives

The aim of this study is to evaluate whether high-flow nasal oxygen is associated with a reduced incidence of hypoxemia compared with low-flow nasal oxygen in adult patients undergoing sedated gastrointestinal endoscopy. The study also aims to assess the impact of the oxygenation strategy on airway interventions and procedural safety in routine clinical practice.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 20/03/2025, Ethics Committee of the National Institute of Emergency Medicine "Pirogov" (21 Tottleben Blvd., Sofia, 1606, Bulgaria; +359 29154411; pirogov@pirogov.bg), ref: EK-04-25/20.03.2025

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study type(s)**

### **Health condition(s) or problem(s) studied**

Hypoxemia during gastrointestinal endoscopy under procedural sedation in adult patients

### **Interventions**

This is a single-center prospective observational cohort study conducted in adult patients undergoing elective gastrointestinal endoscopy under procedural sedation. Patients receive either low-flow nasal oxygen or high-flow nasal oxygen.

Baseline demographic and clinical data are recorded. Continuous monitoring includes pulse oximetry, heart rate, and non-invasive blood pressure. The occurrence of oxygen desaturation and other adverse events is recorded throughout the procedure. Oxygen desaturation is defined as peripheral oxygen saturation below 90 percent. Airway interventions and escalation of oxygen therapy are documented. Statistical analysis is performed to compare outcomes between the two groups and to identify factors associated with desaturation.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

High-flow nasal oxygen delivery system (heated and humidified oxygen therapy) and standard low-flow nasal cannula oxygen therapy

### **Primary outcome(s)**

1. Oxygen desaturation measured using peripheral oxygen saturation by pulse oximetry at the endoscopic procedure from initiation of sedation to procedure completion

### **Key secondary outcome(s))**

1. Apnea measured using respiratory rate monitoring at the endoscopic procedure
2. Bradycardia measured using heart rate monitoring at the endoscopic procedure
3. Laryngospasm measured using clinical assessment by the anesthesiologist at the endoscopic procedure
4. Bronchospasm measured using clinical assessment by the anesthesiologist at the endoscopic procedure

5. Airway interventions measured using need for airway maneuvers at the endoscopic procedure
6. Escalation of oxygen therapy measured using change in oxygen delivery method at the endoscopic procedure
7. Minimal peripheral oxygen saturation measured using pulse oximetry at the endoscopic procedure

**Completion date**

29/08/2025

## Eligibility

**Key inclusion criteria**

1. Adults aged 18 years or older
2. Undergoing elective gastrointestinal endoscopy (upper, lower, or combined)
3. Receiving procedural sedation
4. Inpatients

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

140

**Key exclusion criteria**

1. Emergency procedures
2. Endoscopic retrograde cholangiopancreatography
3. Hemodynamic instability
4. Contraindications to sedation
5. Pregnancy
6. Refusal to participate

**Date of first enrolment**

21/03/2025

**Date of final enrolment**

29/08/2025

## Locations

### Countries of recruitment

Bulgaria

## Sponsor information

### Organisation

National Institute of Emergency Medicine "Pirogov"

### ROR

<https://ror.org/002rp9w47>

## Funder(s)

### Funder type

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not expected to be made available