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Evaluation of the i-gel Plus supraglottic airway device during interventional bronchoscopy: a pilot study

Submission date 06/10/2026	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol
Registration date 04/11/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 04/11/2026	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Supraglottic airway devices are commonly used to keep the airway open and allow ventilation during general anaesthesia. The i-gel Plus is a newer supraglottic airway device based on the established i-gel design. It has separate channels for ventilation and for drainage of gastric contents.

The aim of this pilot study is to evaluate the performance and safety of the i-gel Plus in adult patients undergoing planned interventional bronchoscopy under general anaesthesia. The main aim is to determine how often the device can be inserted successfully and provide effective oxygenation and ventilation within no more than three attempts. The study will also assess insertion time, the need for repositioning, airway seal pressure, oxygen saturation during insertion, difficulty of insertion, and the position of the device in relation to the vocal cords.

Who can participate?

Patients aged over 18 years undergoing planned interventional bronchoscopy under general anaesthesia, for whom airway management with a supraglottic airway device is planned

What does the study involve?

After induction of general anaesthesia, the i-gel Plus will be inserted and used to maintain the airway during the procedure. The research team will record the number of insertion attempts, insertion time, need for repositioning, airway seal pressure, lowest oxygen saturation and the anaesthesiologist's assessment of the difficulty of insertion. A bronchoscope will also be used to assess the position of the device in relation to the vocal cords.

After removal of the device, the research team will record any immediate complications. One hour after waking from anaesthesia, participants will be asked about symptoms such as sore throat, discomfort when swallowing, hoarseness, cough, altered sensation in the mouth or tongue, neck pain and jaw pain.

What are the possible benefits and risks of participating?

Participants are not expected to receive a direct additional health benefit from taking part in the study. The information obtained may help improve our understanding of the performance and

safety of the i-gel Plus during interventional bronchoscopy and may contribute to future airway management practice.
The possible risks are those associated with the use of a supraglottic airway device during general anaesthesia. These may include sore throat, discomfort when swallowing, hoarseness, cough, minor trauma or bleeding, laryngospasm, bronchospasm and, rarely, aspiration of gastric contents.

Where is the study run from?
General University Hospital in Prague (Czech Republic)

When is the study starting and how long is it expected to run for?
October 2026 to July 2027

Who is funding the study?
The study is supported by the Ministry of Health of the Czech Republic through institutional support RVO-VFN 64165

Who is the main contact?
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Contact information

Type(s)
Scientific, Principal investigator, Public

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Additional identifiers

Study information

Scientific Title
Performance and safety of the i-gel Plus supraglottic airway device during elective interventional bronchoscopy: a prospective single-centre pilot study

Study objectives
The primary objective is to evaluate the overall successful insertion rate of the i-gel Plus supraglottic airway device in patients undergoing elective interventional bronchoscopy under general anaesthesia.

Secondary objectives are to characterise device insertion performance, airway seal, fibre optic position relative to the glottis, oxygenation during insertion, and perioperative and early postoperative complications.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/09/2026, Ethics Committee of the General University Hospital in Prague (Na Bojišti 1, 3. patro, Prague, 12808, Czech Republic; +420 (0)224 964 131; eticka.komise@vfn.cz), ref: 148 /26

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Airway management during general anaesthesia for elective interventional bronchoscopy

Interventions
Airway management with the i-gel Plus supraglottic airway device during general anaesthesia for elective interventional bronchoscopy. The device is inserted after induction of general anaesthesia. A maximum of three insertion attempts is permitted, with exchange to another device size if required. Device position is assessed fibre optically after insertion, and oropharyngeal leak pressure is measured immediately after insertion and at 30 and 60 minutes.

Intervention Type
Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
i-gel Plus supraglottic airway device

Primary outcome(s)
1. Successful insertion of the i-gel Plus supraglottic airway device measured using the proportion of participants (%) in whom effective oxygenation and ventilation are achieved with the i-gel Plus within a maximum of three insertion attempts, without a clinically significant audible leak during standard controlled ventilation. Exchange to a different device size is permitted if required. Measured at during induction of general anaesthesia, immediately following insertion of the i-gel Plus

Key secondary outcome(s)
1. Number of i-gel Plus insertion attempts (count; maximum 3) measured using counting each complete removal and reinsertion of the device, including exchange for another device size as a new attempt, at during insertion of the i-gel Plus following induction of general anaesthesia

2. Need for i-gel Plus repositioning measured using the proportion of participants requiring repositioning of the device (%). Repositioning is defined as adjustment of device position without complete removal at during the procedure

3. Oropharyngeal leak pressure (cmH_2O, with a maximum measurement pressure of 40 cmH_2O), measured using the auscultatory method, with recording of the airway pressure (cmH_2O) at which an audible leak occurs, at immediately after device insertion

4. i-gel Plus insertion time measured using time in seconds from passage of the tip of the device between the teeth until connection of the device to the anaesthetic breathing circuit at during device insertion following induction of general anaesthesia

5. No-oxygenation time measured using time in seconds from cessation of face-mask ventilation until appearance of the first visible breath at during airway management following induction of general anaesthesia

6. Lowest peripheral oxygen saturation during device insertion measured using pulse oximetry, expressed as a percentage (%), at during induction of general anaesthesia and insertion of the i-gel Plus

7. Subjective difficulty of i-gel Plus insertion measured using anaesthesiologist-rated difficulty of insertion using a 5-point Likert scale at immediately after successful insertion of the i-gel Plus

8. Fibreoptic position of the i-gel Plus measured using the Fibreoptic View Scoring System (FVSS; score 1–4) and Percentage of Glottic Opening (POGO; 0–100%) at immediately after insertion of the i-gel Plus

9. Airway-related perioperative complications measured using the incidence of blood on the device, gastric contents within/on the device, clinical signs of pulmonary aspiration, laryngospasm, bronchospasm, and other airway-related complications, recorded as present /absent for each event and reported as number and proportion (%) of participants, at removal of the i-gel Plus and at the end of the procedure

10. Early postoperative airway morbidity measured using sore throat, pain/difficulty swallowing, hoarseness, altered sensation of the tongue or oral cavity, external neck pain and jaw pain, each assessed on a numerical rating scale from 0 to 10. Cough is assessed as present/absent and, if present, classified as dry or productive, at 1 hour after emergence from general anaesthesia

Completion date
01/07/2027

Eligibility

Key inclusion criteria
1. Male or female patients
2. Age >18 years
3. American Society of Anesthesiologists (ASA) physical status I–III
4. Scheduled for an elective interventional bronchoscopy procedure with planned airway management using a supraglottic airway device

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Months

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Age <18 years
2. Emergency procedure
3. Increased risk of pulmonary aspiration of gastric contents
4. Body mass index (BMI) >35 kg/m²
5. Non-standard procedural position (head-down/Trendelenburg, prone or sitting position)
6. Inability to understand and/or sign the informed consent form, including due to cognitive impairment or a language barrier

Date of first enrolment
01/10/2026

Date of final enrolment
01/04/2027

Locations

Countries of recruitment
Czech Republic

Study participating centre
General University Hospital in Prague
U Nemocnice 2
Prague
Czech Republic
12808

Sponsor information

Organisation
General University Hospital in Prague

ROR
https://ror.org/04yg23125

Funder(s)

Funder type

Funder Name
Ministerstvo Zdravotnictví Ceské Republiky

Alternative Name(s)
Ministry of Health of the Czech Republic, MZCR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Czech Republic

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	31/08/2026	06/10/2026	No	No