# STUDY PROTOCOL

# i-gel Plus Supraglottic Airway Device in Interventional Bronchoscopy – Pilot Study

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**Collaborating centres:** None

## Introduction

The i-gel Plus is a new airway device intended for airway management during anaesthesia in fasted patients undergoing elective surgical procedures (Appendix 1). The device fulfils the requirements for clinical use in European Union countries, including the Czech Republic. Technologically, it is based on established second-generation supraglottic airway devices, i.e. devices incorporating a separate ventilation channel and an additional channel for active or passive drainage of gastric contents. In design, the i-gel Plus is similar to the original i-gel device, which has been routinely used for airway management during general anaesthesia since 2007.

## Study type

Prospective cohort, interventional study (the intervention is comparable to other procedures performed under general anaesthesia with airway management). This is a single-centre pilot study conducted at one centre in the Czech Republic. The General University Hospital in Prague is the initiator and organiser of the study. The study is supported by the Ministry of Health of the Czech Republic, RVO-VFN 64165.

## Study objective

To evaluate the success rate of i-gel Plus insertion, insertion time, oropharyngeal leak pressures, quality of glottic view, and the incidence of perioperative and postoperative complications in male and female patients scheduled for elective interventional bronchoscopy with planned airway management using a supraglottic airway device.

## Planned methodology

1. The day before the planned procedure, the patient will be approached and informed about the possibility of participating in the study. The Participant Information Sheet will be provided and sufficient time will be allowed for consideration. The patient will be enrolled no later than the morning of the procedure after signing the Informed Consent Form.

2. During the preoperative phase, demographic data will be recorded: age, sex, body weight, height, body mass index (BMI), American Society of Anesthesiologists (ASA) physical status, comorbidities and dental status.

3. The type of procedure and the patient's position during the procedure will be recorded.

4. The anaesthesiologist's experience will be recorded as the previous number of insertions of standard supraglottic airway devices.

5. Induction of anaesthesia will be performed according to standard practice using intravenous propofol, a potent opioid analgesic and a neuromuscular blocking agent.

6. Anaesthesia will be maintained using an oxygen/air carrier gas mixture and total intravenous anaesthesia (TIVA) with target-controlled infusion (TCI).

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7. All patients will undergo standard monitoring including non-invasive blood pressure measurement, electrocardiography, pulse oximetry and capnography. Extended monitoring will be used when clinically indicated.

8. Following insertion, the position of the device in relation to the vocal cords will be assessed fibreoptically by the interventional bronchoscopist.

9. A gastric tube will not be inserted in the indicated patients.

10. Primary and secondary outcomes will be assessed after device insertion. Oropharyngeal leak pressure will be measured after insertion and at 30 and 60 minutes after insertion.

11. After removal of the device, immediate perioperative complications such as blood on the device and gastric contents on/in the device will be recorded.

12. Postoperative assessment will be performed 1 hour after emergence from anaesthesia.

## Inclusion criteria

- Male and female patients
- Age >18 years
- ASA physical status I–III
- Elective interventional bronchoscopy with planned airway management using a supraglottic airway device

## Exclusion criteria

- Age <18 years
- Emergency procedure
- Increased risk of aspiration of gastric contents
- BMI >35 kg/m²
- Non-standard procedural position – head-down, prone or sitting position
- Inability to understand and/or sign the informed consent form (cognitive impairment, language barrier)

## Primary outcome

- Overall successful insertion of the device (%)

## Measurement of the primary outcome

Successful insertion is defined as the i-gel Plus providing effective oxygenation and ventilation within a maximum of three insertion attempts, without a clinically significant audible leak during standard controlled ventilation. Exchange to a different device size (smaller to larger or vice versa) is permitted as clinically required.

## Secondary outcomes

- Number of insertion attempts (maximum 3)
- Repositioning
- Oropharyngeal leak pressure ($cmH_2O$; maximum 40 $cmH_2O$)
- Insertion time (seconds)
- No-oxygenation time (seconds)
- Lowest peripheral oxygen saturation measured by pulse oximetry ($SpO_2$, %)
- Subjective assessment of insertion difficulty (5-point Likert scale)
- Fibreoptic assessment of device position

## Measurement of secondary outcomes

- **Number of insertion attempts –** Each complete removal and reinsertion of the device, including exchange of the device, will be counted as an insertion attempt. Adjustment of device position during the procedure in the presence of a minor leak without removal of the device will be classified as repositioning.
- **Oropharyngeal leak pressure –** Measured after insertion of the device.

- **Insertion time –** Measured from the moment the tip of the device passes between the teeth until connection to the breathing circuit of the anaesthesia machine.
- **No-oxygenation time –** Measured from cessation of face-mask ventilation until appearance of the first capnographic waveform on the capnograph.
- **Lowest $SpO_2$ –** The lowest peripheral oxygen saturation recorded during induction of anaesthesia and device insertion.
- **Subjective assessment of insertion difficulty –** A 5-point Likert scale will be used: 1 = very easy, 2 = rather easy, 3 = neither easy nor difficult, 4 = rather difficult, 5 = very difficult.
- **Fibreoptic assessment of device position –** The endoscope will be advanced through the device to the end of the dedicated channel. Device position will be assessed using the scoring system shown in Appendix 2 and the Percentage of Glottic Opening (POGO) score. Fibreoptic assessment will be performed in all participants.

### At the end of the procedure

- Complications – blood on the device, gastric contents within/on the device, clinical signs of aspiration, laryngospasm, bronchospasm, and other complications.

### Postoperative assessment

- Sore throat (1–10 scale)
- Pain/difficulty swallowing (1–10 scale)
- Hoarseness (1–10 scale)
- Altered sensation of the tongue or oral cavity (1–10 scale)
- Cough (yes/no; dry/productive)
- External neck pain (1–10 scale)
- Jaw pain (1–10 scale)

### Data collection

Data will be entered into a computer database and analysed statistically. Data anonymity will be strictly maintained.

### Statistics

A total of 60 patients will be enrolled at one centre in the Czech Republic as part of this pilot study. An overall insertion success rate of at least 90–95% is anticipated, corresponding to a failure rate of 5–10%, based on published studies of modern supraglottic airway devices (reference 4).

### Study timeline

Six months for study conduct and data collection, followed by 3 months for analysis of the results.

### References

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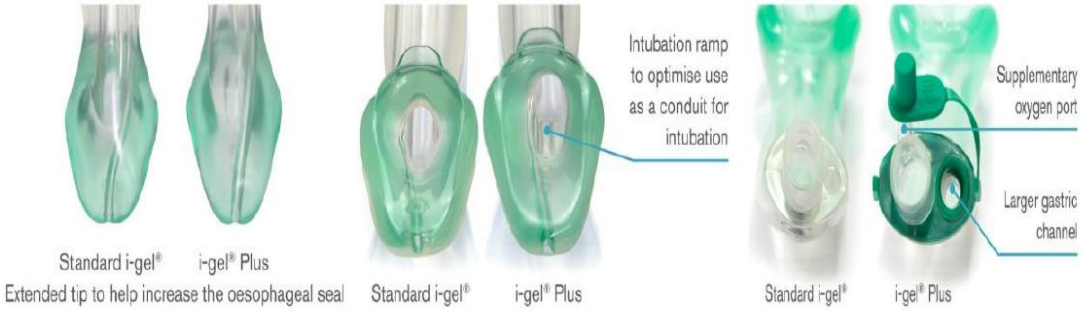
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## Appendix 1: i-gel Plus supraglottic airway device




## Appendix 2

Table 1 – Fibreoptic View Scoring System through a supraglottic airway device (Kapila et al., 1997) and Percentage of Glottic Opening (POGO) score (Levitan et al., 1998)

| Fibreoptic View Scoring System (FVSS) | View |
|---|---|
| 1 | Vocal cords fully visible |
| 2 | Vocal cords partially visible, including the arytenoid cartilages |
| 3 | Only the epiglottis visible |
| 4 | Only other structures visible (pharynx, laryngeal mask cuff) |
| POGO score | View |
| 0 | Vocal cords not visible |
| 1–99 | Vocal cords partially visible (value corresponds to the proportion of the vocal cords visible on the monitor) |
| 100 | Vocal cords fully visible |



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