

# The evaluation of the insertion parameters and complications of the i-gel Plus airway device for maintaining patent airway during planned procedures under general anaesthesia

<b>Submission date</b> 26/11/2019	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/12/2019	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/03/2023	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

The aim of this study is to evaluate a new modification of the device used for maintaining a patent airway during procedures under general anaesthesia. This device is the i-gel Plus and it belongs among the supraglottic airway devices. The i-gel Plus device is used for elective procedures and for patients at low risk of gastric content aspiration. The aim is to evaluate the efficacy, insertion characteristics and perioperative/postoperative complications associated with the use of this device.

### Who can participate?

Patients indicated for any procedure under general anaesthesia, both genders, aged 18-89, without a significant medical condition.

### What does the study involve?

All participants receive identical treatment - intravenous induction to general anaesthesia using routinely used medication and insertion of the i-gel Plus device to the mouth to maintain patent airway during the procedure. At the end of surgery, the i-gel Plus is removed, any blood or gastric fluid on the device is noted and recorded. Postoperative complications are recorded after 1 hour and 24 hours.

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

The new device is expected to have a high success rate and a low incidence of adverse effects. Risks are similar to other devices used for maintaining patent airway: sore throat, pain on swallowing after the operation.

### Where is the study run from?

This study will be performed in seven centres across Europe - three in the Czech Republic (two in

Prague, one in Olomouc), one in Poland (Lodz), one in Switzerland (Bern), one in Spain (Barcelona), two in the United Kingdom (Antrim, Craigavon). The lead centre is the General University Hospital in Prague, Czech Republic.

When is the study starting and how long is it expected to run for?  
September 2019 to December 2024

Who is funding the study?

The study is partially funded by the Czech Ministry of Health through the Institutional Support Grant. Other funding comes from the centers/departments involved in the study.

Who is the main contact?

Prof. Pavel Michalek  
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## Contact information

### Type(s)

Scientific

### Contact name

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### Type(s)

Public

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

U1111-1244-3085

# Study information

## Scientific Title

A prospective evaluation of the i-gel Plus supraglottic airway device in elective procedures

## Acronym

i-gel Plus

## Study hypothesis

Hypothesis: Total success rate of device insertion will be at least 96%.

Evaluation of total success rate, insertion parameters, perioperative and postoperative complications associated with the insertion of a novel supraglottic airway device i-gel Plus.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Approved 14/11/2019, Eticka komise Vseobecne fakultni nemocnice v Praze (Ethics Committee of the General University Hospital in Prague) (Na Bojišti 1, 12808 Praha 2, Czech Republic; Tel: +420 (0)224964131; Email: eticka.komise@vfn.cz), ref: 1952/19 S-IV
2. Approved 10/02/2020, University Hospital Olomouc (Etická komise FN a LF UP Olomouc, I. P. Pavlova 185/6, 779 00 Olomouc, Czech Republic; +420 (0) 588 442 477; iveta.sudolska@fnol.cz), ref: 18/20
3. Approved 03/03/2020, University Hospital in Lodz (Komisja Bioetyczna przy Uniwersytecie Medycznym w Łodzi, Pl. Hallera 1B II piętro pok. 230, 90-647 Łódź, Poland; +48 (0) (42) 272-52-43, (42) 272-52-44, 785-911-596; bioetyka@umed.lodz.pl), ref: RNN/61/20/KE
4. Approved 08/09/2020, University Hospital in Barcelona (Comité de Ètica de la Investigación con medicamentos del Hospital Clínic de Barcelona, Hospital Clínic De Barcelona Villarroel, 170 – 08036 Barcelona, Spain; +34 (0)932275766; ceic@clinic.cat), ref: HCB 2020/0771
5. Approved 10/12/2020, Northern HSC Trust for Antrim Area Hospital in Antrim (Research and Development Office, Governance Department, Bush House, Antrim Area Hospital, Bush Road, , BT41 2QB, Northern Ireland; +44 (0)28 9442 4653; frances.johnston@northerntrust.hscni.net), ref: NT20-278410-10
6. Approved 22/04/2021, Southern HSC Trust for Craigavon Area Hospital (Research and Development Office, Southern Health & Social Care Trust, Ramone Building, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ, Northern Ireland; +44 (0)28 3861 4274; research.office@southerntrust.hscni.net), ref: ST2021/31

7. Approved 27/11/2020, Office for Research and Ethical Committee Northern Ireland (ORECNI; 5 Rathdown Walk, Lisburn BT28 2RF, United Kingdom/Northern Ireland; +44 (0)28 9536 1400; info.orecni@hscni.net), ref: REC 20/NI/0140

8. Approved 21/12/2020, University Military Hospital in Prague (Etická komise Ústřední vojenské nemocnice – Vojenské fakultní nemocnice Praha, U Vojenské nemocnice 1200, 169 02 Praha 6, Czech Republic; +420 (0)973 203 550; nina.vesela@uvn.cz), ref: 108/15-104/2020

### **Study design**

Multicentre interventional prospective cohort study. No control

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

### **Study setting(s)**

Hospital

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

Treatment

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

### **Condition**

Airway management in patients under general anaesthesia

### **Interventions**

Intravenous induction with propofol, opioid (fentanyl, sufentanil). Muscle relaxant is not a part of the protocol. If given, for any reason, this must be reported to the CRF. Maintenance – air, oxygen, sevoflurane, boluses of opioid, non-opioid analgesics, controlled ventilation.

Monitoring – routine – ECG, NIBP, pulse oximetry, capnography, invasive monitoring as per the case. Respiratory – peak pressures, plateau pressures, compliance.

At the end of surgery, the i-gel Plus will be removed, any blood or gastric fluid on the device noted and recorded. Postoperative complications will be followed at 1 hour and 24 hours.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Primary outcome measure**

Success rate of device insertion (%), defined as the device providing effective oxygenation and ventilation without a significant leak. Timepoint: After device insertion, after induction to general anaesthesia.

### **Secondary outcome measures**

1. Number of attempts (maximum three allowed). Timepoint: after induction to general anaesthesia
2. Oropharyngeal seal (leak) pressure (cmH2O, maximum 40 cmH2O). Timepoint: measured after insertion, at 30, 60 mins.
3. Insertion time (sec), measured from inserting the device between the teeth until connection to the anaesthetic machine. Timepoint: after induction to general anaesthesia.
4. Subjective assessment of insertion ease, measured using a 1-5 Likert scale. Timepoint: after insertion of the device.
5. Fiberoptic assessment of the device position, measured using a scale 1-4 (1- full view of the vocal cords, 2- partial view of the vocal cords only, 3- only epiglottis visible, 4- not even epiglottis visible). Timepoint: after device insertion. Note: this secondary outcome is eligible, it depends on the availability of flexible bronchoscope.
6. Insertion of the gastric tube measured using a 1-5 Likert scale. Timepoint: after insertion of the device. Note: this secondary outcome is eligible, it depends on clinical indication.
7. Perioperative complications – blood on the device, gastric contents inside the bowl, clinical signs of aspiration, laryngospasm, bronchospasm. Timepoint: at the end of the procedure, after the i-gel Plus removal.
8. Postoperative complications:
  - 8.1. Sore throat (1-10 scale)
  - 8.2. Pain on swallowing, swallowing difficulties (1-10 scale)
  - 8.3. Hoarseness (1-10 scale)
  - 8.4. Numb tongue, numbness inside the oral cavity (1-10 scale)
  - 8.5. Cough
  - 8.6. Neck pain (1-10 scale)
  - 8.7. Jaw pain (1-10 scale)Timepoint: Measured by questionnaire at 1 and 24 hours post-procedure. Selected patients showing significant complaints at 24 hours will be contacted by telephone at 3 and 6 months after the procedure.

**Overall study start date**

01/09/2019

**Overall study end date**

31/12/2024

## Eligibility

**Participant inclusion criteria**

1. Males or females
2. Age 18-89 years
3. American Society of Anesthesiologists classification (ASA) I-III status
4. Elective procedure without a need for muscle relaxation

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

89 Years

**Sex**

Both

**Target number of participants**

2000

**Participant exclusion criteria**

1. Age less than 18 or more than 89 years
2. American Society of Anesthesiologists classification (ASA) more than III status
3. Emergency surgery
4. Intra-abdominal operations, intrathoracic procedures
5. Increased risk for aspiration of gastric contents
6. BMI of more than 35 kg/m<sup>2</sup>
7. Unusual operating positioning – steep head down, prone, sitting
8. Incapacity to understand/sign informed consent (learning difficulties, language difficulties)

**Recruitment start date**

23/09/2020

**Recruitment end date**

30/11/2024

**Locations****Countries of recruitment**

Czech Republic

Northern Ireland

Poland

Spain

United Kingdom

**Study participating centre**

**Vseobecná fakultní nemocnice v Praze (General University Hospital in Prague)**

U nemocnice 2

Prague

Czech Republic

12808

**Study participating centre**

**Fakultni nemocnice Olomouc (University Hospital in Olomouc)**

I.P. Pavlova 185/6

Olomouc

Czech Republic

77900

**Study participating centre**

**Barlicki University Hospital in Lodz**

Kopcinskiego 22

Lodz

Poland

PL91-153

**Study participating centre**

**Antrim Area Hospital, Northern HSC Trust**

Bush Road

Antrim

United Kingdom

BT41 2RL

**Study participating centre**

**Craigavon Area Hospital, Southern HSC Trust**

68 Lurgan Road

Portadown

United Kingdom

BT63 5QQ

**Study participating centre**

**Ustredni vojenska nemocnice/Vojenska fakultni nemocnice v Praze (Central Military Hospital /Military University Hospital in Prague)**

U vojenske nemocnice 1200

Prague

Czech Republic

16902

**Study participating centre**

**Hospital Clinic de Barcelona/University Hospital in Barcelona**

C. de Villarroel

Barcelona

Spain

170 08036

# Sponsor information

## Organisation

Vseobecna fakultni nemocnice (General University Hospital)

## Sponsor details

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## Sponsor type

Hospital/treatment centre

## Website

<https://www.vfn.cz/>

## ROR

<https://ror.org/04yg23125>

# Funder(s)

## Funder type

Government

## Funder Name

Czech Ministry of Health MZCZ-DRO-VFN64165

# Results and Publications

## Publication and dissemination plan

Current publication and dissemination plan as of 24/09/2021:

1. Publication of the protocol: BMC Anesthesiology or BMJ Open 12/2021
2. Presentation of the results: anaesthetic conference in 2023
3. Publication of raw data 07/2023 - <https://www.mendeley.com>
4. Publication: anaesthetic journal with an Impact Factor, submission 12/2023

Previous publication and dissemination plan from 16/10/2020 to 24/09/2021:

1. Publication of the protocol: BMC Anesthesiology or BMJ Open 12/2021



2. Presentation of the results: anaesthetic conference in 2022
3. Publication of raw data 07/2022 - <https://www.mendeley.com>
4. Publication: anaesthetic journal with an Impact Factor, submission 12/2022

Original publication and dissemination plan:

1. Publication of the protocol: BMC Anesthesiology 03/2020
2. Presentation of the results: anaesthetic conference in 2021
3. Publication of raw data 07/2021 - <https://www.mendeley.com>
4. Publication: anaesthetic journal with an Impact Factor, submission 12/2021

### Intention to publish date

01/06/2025

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository Mendeley (<https://data.mendeley.com>). Type of data that will be shared: raw data, anonymized, demographics: gender, age, height, weight, BMI, procedure, duration; insertion parameters (as stated in the primary and secondary outcomes for the study), postoperative complications. When the data will become available, and for how long: after completion of the study, permanently. By what access criteria the data will be shared including with whom, for what types of analyses, and by what mechanism, whether consent from participants was obtained, comments on data anonymisation, any ethical or legal restrictions, any other comments: publicly available data, availability for everybody - secondary statistical analysis, systematic reviews, meta-analysis, consent from participants obtained for the publishing of anonymized raw data, data anonymized according to the GDPR legal regulations in the Czech Republic and EU, no other ethical/legal regulations).

### IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol (preprint)</a>		22/07/2021	24/09/2021	No	No
<a href="#">Protocol article</a>		20/12/2021	22/12/2021	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No