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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

Submission date
26/11/2019

Recruitment status
No longer recruiting

Registration date
16/12/2019

Overall study status
Ongoing

Last Edited
21/01/2025

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

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 2025

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

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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 objectives
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 Ética 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.

Health condition(s) or problem(s) studied
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
Procedure/Surgery

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 (cmH20, maximum 40 cmH20). 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

Completion date
31/12/2025

Eligibility

Key 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

Key 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/m2
7. Unusual operating positioning – steep head down, prone, sitting
8. Incapacity to understand/sign informed consent (learning difficulties, language difficulties)

Date of first enrolment
23/09/2020

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
Czech Republic

Northern Ireland

Poland

Spain

United Kingdom

Study participating centre
Vseobecna fakultni 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
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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
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170 08036

Sponsor information

Organisation
Vseobecna fakultni nemocnice (General University Hospital)

Sponsor details
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12028
+420 (0)224962243
jan.blaha@vfn.cz

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
01/06/2026

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?
Protocol (preprint)		22/07/2021	24/09/2021	No	No
Protocol article		20/12/2021	22/12/2021	Yes	No
HRA research summary			26/07/2023	No	No