University Hospitals Coventry and Warwickshire NHS Trust

Fibre-optic guided tracheal intubation through supraglottic airway devices – a randomised comparison between I-gel® and the LMA Protector™

Fibre-optic guided tracheal intubation through SAD's

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Research Governance Framework, the ICH Good Clinical Practice guidelines and the Sponsor's SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

..../……/……..

Name (please print):

.....

Position:

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Chief Investigator:

Signature: Date:

..... ……/……../……..

Name: (please print):

Prof. Cyprian Mendonca

Position: Consultant Anaesthetist

KEY TRIAL CONTACTS

Chief Investigator	Professor Cyprian Mendonca Department of Anaesthesia University Hospital, Coventry, CV2 2DX Contact no: 02476964000 bleep 1865
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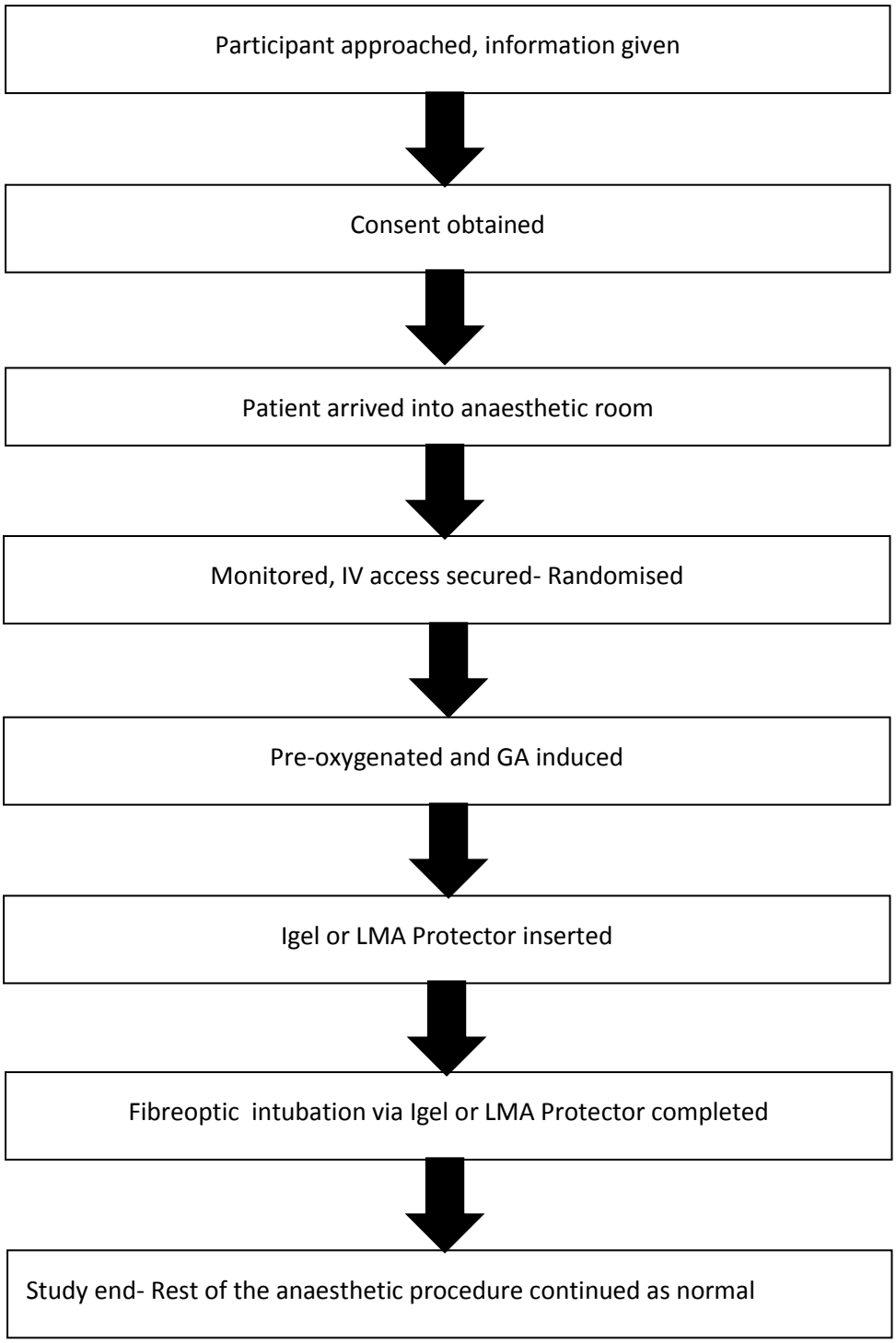
TRIAL SUMMARY

Full study title	Fibre-optic guided tracheal intubation through supraglottic airway devices – a randomised comparison between I-gel® and the LMA Protector™	
Short study title	Fibre-optic guided tracheal intubation through SAD's	
Trial Design	Multi – centre randomised	
Trial Participants	All patients aged 18 and above, presenting for elective surgical procedure where a supraglottic airway device can be used.	
Planned Sample Size	180 across 2 sites	
Follow up duration	0 months	
Planned Trial Period	12-14months	
	Objectives	**Outcome Measures**
Primary	Successful tracheal intubation	Time form insertion of from insertion of scope till end-tidal CO_2
Secondary	Successful placement of supra-glottic airway device	Number of attempts Time taken to insert supra-glottic airway device

Key Words: Intubation; tracheal, airway device; supra-glottic airway device, fibreoptic scope.

TRIAL FLOW CHART

Figure 1: Flow of participants through the study



SCHEDULE OF OBSERVATIONS

Table 1: Schedule of measures

SAD insertion time (from insertion into the mouth of until 1st capnography trace is obtained)
SAD insertion score: 1-easy, 2 – mild difficulties, 3 – difficult, 4 - failure
SAD insertion attempts
Leak pressure: pressure at which audible leak starts, set flow at 6L/ mins and increase the APL valve pressure.
FOI: View grade grade I – full view of the vocal cord, II – partial view of the vocal cords & arytenoids, III – epiglottis only, IV – other (SAD cuff, pharynx, others)
FOI: **Time to view carina:** time from insertion of scope into the SAD lumen ending with visualization of the carina
FOI: Total intubation time (from insertion scope through SAD until 1st capnography trace is obtained)
No of attempts at intubation
Operator's visual analogue score: 0 to 10 (0 being very difficult, 10 being very easy)
Difficulty observed: tube rotation, tube impingement, failure to intubate
Surgery:
Duration of surgery in minutes

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LIST OF ABBREVIATIONS

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CI	Chief Investigator
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
ISF	Investigator Site File
NHS R&D	National Health Service Research & Development
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAD protector)	Supraglottic Airway device (Igel and LMA
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File

STUDY PROTOCOL

Fibre-optic guided tracheal intubation through supraglottic airway devices – a randomised comparison between I-gel® and the LMA Protector™

1. INTRODUCTION

Intubation through supraglottic airway devices (SAD) is a well-established technique in the management of patients with difficult airway. The passage of the endotracheal tube into the trachea using the SAD as a conduit can be performed blindly or with the use of a fiberoptic scope to guide intubation. The recently-published "Difficult Airway Society guidelines for management of unanticipated difficult intubation in adults" strongly emphasise the importance of minimising the number of airway interventions during a difficult airway scenario [1]. Hence, it is recommended that blind technique, with its lower success rate should no longer be used. In a patient where tracheal intubation is planned and when the initial plan (plan A) fails guideline recommends declaring the failure and moving on to plan B. Plan B involves securing the airway using a second a SAD. Guideline recommends use of second generation SAD due to added benefit of minimising gastric aspiration. Once the situation is stable, tracheal intubation can be performed through SAD using fiberoptic scope (camera device).

There are two second generation supraglottic airway devices, currently available: I-gel® and LMA Protector™ that allow tracheal intubation.

The I-gel is a second generation supraglottic airway device widely used in anaesthesia and resuscitation. Fiberoptic intubation through the I-gel has been evaluated in a recent prospective study, with the first attempt success rate of 91.4% (Taxak). In another study of patients with predicted difficult airway the success rate of the procedure at first attempt was 96%. (Kleine-Brueggeney)

LMA Protector is a recently introduced improved version LMA supreme another second generation supraglottic airway device. LMA supreme has been used in clinical practice for more than 10 years. But tracheal intubation through LMA supreme was extremely difficult because of the smaller breathing channel. Hence the improvised version has larger breathing channel. Compared to I-gel, this has larger gastric drainage tube and allows easy suction in the event of regurgitation. Therefore, in preventing the aspiration risk, LMA protector device appears to be superior to I-gel.

We are not aware of any study comparing these two devices for fiberoptic (camera) assisted tracheal intubation.

Comparing the efficacy of these devices in adults could in future guide the anaesthetists' choice of the SAD used in the difficult airway scenario, and also help the anaesthetists take informed decisions when using SADs to intubate the trachea in elective settings.

2. RATIONALE

2.1 Aims and hypothesis

The aim of this study is to compare the fiberoptic guided tracheal intubation through I gel supraglottic airway to that of LMA protector supraglottic airway device. Our hypothesis is that intubation through I – gel is easier and quicker.

Justification

The recently-published "Difficult Airway Society guidelines for management of unanticipated difficult intubation in adults" strongly emphasise the importance of minimising the number of airway interventions during a difficult airway scenario. When the initial plan (Plan A) of tracheal intubation (process of placing the breathing tube in to the wind pipe using initial method) fails, one should move on to plan B. Plan B involves placing supraglottic airway device and maintaining oxygenation. Once the oxygenation is stable, further attempt at intubation can be performed through the supraglottic airway device using fiberoptic scope. Supraglottic Airway Device-a type airway tube placed in the oral cavity (oropharynx) is used as conduit for passing the camera known as fiberoptic scope. Once the fiberoptic scope is placed in the wind pipe, the tracheal tube is railroaded over the fiberoptic scope.

DAS guidelines recommend to use second generation supraglottic airway device. The key feature of second generation supraglottic airway device is the ability to minimise the risk of aspiration.

The I-gel is a second generation supraglottic airway device widely used in anaesthesia and resuscitation. LMA Protector is a recently introduced improved version LMA supreme another second generation supraglottic airway device. LMA supreme has been used in clinical practice for more than 10 years. But tracheal intubation through LMA supreme was difficult because of the smaller breathing channel. Hence the improvised version has larger breathing channel. The LMA protector has a larger breathing channel and hence can be used a conduit for tracheal intubation. Compared to I-gel, LMA protector has a larger gastric drainage tube and allows easy suction in the event of aspiration. Therefore, in preventing the aspiration risk, LMA protector device appears to be superior to I-gel.

The data comparing the efficiency of fibre-optic guided intubation using the above supraglottic airway devices in adults are so far lacking. Comparing the efficacy of these devices in adults could in future guide the anaesthetists' choice of the supraglottic airway device used in the difficult airway scenario, and also help the anaesthetists take informed decisions when using SADs to intubate the trachea in elective settings.

2.3 Assessment and management of risk

Supraglottic airway device routinely used in clinical practice as an airway during general anaesthesia involving minor surgery. For this study patients requiring general anaesthesia and tracheal intubation will be selected. We do not anticipate any additional risks or benefits to the study participants. During the process of intubation, peripheral oxygen saturation is closely monitored.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Primary objective

The aim of the study is to establish which of the two Supraglottic Airway Devices (a type airway tube placed in the oral cavity) is best suited for tracheal intubation (the process of placing the breathing tube in to the wind pipe). The process of placing the breathing tube is guided using fibre-optic scope (a camera device) through the Supraglottic Airway Device. The primary outcome of this will be time to complete the intubation.

Supraglottic Airway Device (a type airway tube placed in the oral cavity/oropharynx) is used as conduit for passing the camera (known as fiberoptic scope) to the wind pipe. Once the fiberoptic scope is paced in the wind pipe, the tracheal tube is railroaded over the fiberoptic scope and fiberoptic scope is removed. The breathing tube is then connected to the anaesthetic machine.

3.2 Secondary objectives

The results of the study should reveal whether there is a significant difference in the ease of intubation (the process of placing the breathing tube in to the wind pipe) and success rate between two supraglottic airway devices.

3.3 Primary endpoint/outcome

Time to successful tracheal intubation: defined as the duration of time from insertion of scope through the supraglottic airway device, ending with the observation of a first square wave end-tidal capnography trace.

3.4 Secondary endpoints/outcomes

- Number of attempts at the SAD placement
- SAD insertion time: defined as the duration of time SAD picked up in the hand, ending with the observation of a first square wave end-tidal capnography trace.
- Number of attempts at tracheal intubation
- The ease of placement of the SAD; 1-easy, 2 – mild difficulties, 3 – difficult, 4 - failure
- The fiberoptic quality of the laryngeal view (seen through the SAD) will be assessed, according to the previously published system, as: grade I – full view of the vocal cord, II – partial view of the vocal cords including arytenoids, III – epiglottis only, IV – other (SAD cuff, pharynx, others) (Joffe 2011)
- Time to carinal view: defined as the duration of time from insertion of scope into the SAD lumen ending with visualization of the carina.
- The number and type of airway manoeuvres performed during tracheal intubation
- Peri-operative complications

4 TRIAL DESIGN

Multi-centre randomised-controlled trial

5 STUDY SETTING

The study will be conducted in 2 hospitals in England. University Hospitals Coventry & Warwickshire NHS Trust and Oxford University Hospitals.

6 ELIGIBILITY CRITERIA.

6.1 Inclusion criteria

All patients aged above 18, presenting for elective surgical procedure, where a supraglottic airway device can be used and left in place throughout the duration of surgery and requiring tracheal intubation will be invited to take part in the study. This involves a group of patients presenting for abdominal surgery and peripheral limb operation where tracheal intubation is indicated.

6.2 Exclusion criteria

- Patients who are do not want to take part or do not give consent
- Patients with class II obesity (BMI >40)
- Patients below 18 years of age
- ASA 3, 4 and 5,
- Patients with mouth opening of less than 3 cm

- Patients deemed to require awake intubation
- Surgery involving head and neck region
- Surgery requiring prone position

7 TRIAL PROCEDURES

The suitable patients for the study will be screened from the operating theatre list. During the preoperative assessment one of the investigator or co-investigator will provide patient information sheet. Patients will be given adequate time to read the information and any questions will be answered. If they are satisfied and willing to take part in the study, written consent will be obtained.

7.1 Recruitment

Both Chief investigator and co-investigators identify the suitable operating list. Then the suitable patients will be identified based on the scheduled surgical procedure. Only those patients meeting the inclusion criteria will be approached.

7.1.1 Patient identification

The patients undergoing surgery that requires tracheal intubation are suitable to be included in the study. Based on the scheduled surgery on the operating list, the suitable patients will be identified. During the preoperative assessment one of the investigator or co-investigator will provide patient information sheet. Patients will be given adequate time to read the information and any questions will be answered. If they are satisfied and willing to take part in the study, written consent will be obtained.

7.2 Consent

Participants will be given enough time to read the patient information leaflet (minimum of 2 hours). Once they have read the information, any questions will be answered. If they agree for the study, they will be asked to complete the consent form. The consent will be obtained by chief investigator, coinvestigator or one of the research team member, supervised by one of the investigator.

7.3 Randomisation scheme

Randomisation for this study will be completed on a 1:1 basis via sealed envelopes. The Statistician will create 2 master randomisation lists for each site and the envelopes will be numerically ordered.

On arrival to the anaesthetic room, sealed envelope will be opened to reveal the group. Based on the group, following induction of general anaesthesia, the chosen supraglottic airway device will be inserted. Once the supraglottic airway device placement confirmed, tracheal intubation is completed using Fiberoptic scope.

The randomisation will determine which supraglottic airway device to choose. Rest of the process is similar in both groups.

In theatre once the envelopes have been opened the randomisation log will need to be completed. The envelopes containing the assigned device will be retained in a folder in theatre.

7.5 Baseline data

Base line data includes gender, age, weight, height, BMI & ASA score

Airway assessment includes Mallampati score, thyromental distance, mouth opening and neck movement

7.6 Trial assessments

Time taken to insert supraglottic airway device
Ease of SAD insertion and number of attempts
View of the larynx through fiberoptic scope
Time to view the carina (end of wind pipe)
Total intubation time
No of attempts
Anaesthetist's visual analogue score on the ease of procedure
Any additional manoeuvres required such as tube rotation or jaw thrust

8 DATA HANDLING

8.1 Data collection tools and source document identification

CRFs will completed at the time of data collection

No other data collection is required

8.2 Data handling and record keeping

Consent forms and CRFs will be filed into the investigator site file and the data is then entered at regular interval into the excel sheet on an encrypted NHS computer.

8.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections.

8.4 Archiving

Research data will be stored off site in a secure approved NHS access facility - TNT. Only the research team will have authority to access this data if required via a request to the R&D Archiving Team. The study will be archived for 25 years from the close of the study with a review 1 year before the anticipated destruction date

9. TRIAL OVERSIGHT

9.1 Role and responsibilities of the Sponsor

UHCW has agreed to act as sponsor for this trial and will undertake the responsibilities of sponsor as defined by the Research Governance Framework and ICH Good Clinical Practice. An authorised representative of the Sponsor has approved the final version of this protocol with respect to the trial design, conduct, data analysis and interpretation and plans for publication and dissemination of results. As sponsor, UHCW provides indemnity for this trial and, as such, will be responsible for claims for any non-negligent harm suffered by anyone as a result of participating in this trial. The indemnity is renewed on an annual basis and will continue for the duration of this trial.

9.2 Principal Investigators

"Site Principal Investigator responsibilities include, but are not limited to:

- Ensuring that the trial is conducted as set out in the protocol and supporting documents
- Delegating trial related responsibilities only to suitably trained and qualified personnel and ensuring that those with delegated responsibilities fully understand and agree to the duties being delegated to them;
- Ensuring that CVs and evidence of appropriate training for all Site staff are available in the Trial Site File
- Ensuring that all delegated duties are captured in the study Delegation Log
- Ensuring the trial is conducted in accordance with ICH GCP principles;
- Allowing access to source data for monitoring, audit and inspection;
- Ensuring that all source data is complete and provided to the chief investigator

10. MONITORING, AUDIT & INSPECTION

The study will be monitored by the Research & Development department at UHCW as representatives of the Sponsor, to ensure that the study is being conducted as per protocol, adhering to Research Governance and GCP. The approach to, and extent of, monitoring will be specified in a trial monitoring plan determined by the risk assessment undertaken prior to the start of the study."

11. ETHICAL AND REGULATORY CONSIDERATIONS

11.1 Ethical approval and research governance

The study will be conducted in compliance the principles of the ICH GCP guidelines and in accordance with all applicable regulatory guidance, including, but not limited to, the Research Governance Framework. Ethical approval for this study will be sought from the Research Ethics Committee combined with Health Research Authority (HRA) approval. No study activities will commence until favourable ethical opinion and HRA approval has been obtained. Progress reports and a final report at the conclusion of the trial will be submitted to the approving REC within the timelines defined by the committee. Confirmation of capacity and capability will be obtained from the R&D departments obtained prior to commencement of the study at all participating sites.

11.2 Peer review

One external and internal review has been completed.

11.4 Data protection and patient confidentiality

The study will comply with the Data Protection Act 1998. Participants will be assigned a unique identifier upon enrolment in to the study to allow link-anonymisation of patient-identifiable data. Access to patient identifiable data will be restricted to members of the study co-ordination team who require it for the performance of their role. Electronic data will be stored on password protected encrypted drives and hard copies of study documents will be stored in locked filing cabinets in secure entry-card protected sites.

12 DISSEMINATION POLICY

The study finding will be first presented as an abstract at national meetings and subsequently published in Anaesthesia peer reviewed journal.

13 REFERENCES

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