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Infrared guided placement of a breathing tube before surgery

Submission date	Recruitment status	[_] Prospectively registered
06/08/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/08/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/09/2021	Surgery	

Plain English summary of protocol

Background and study aims
All anaesthesia requires the safe provision of oxygen and anaesthesia gases. These are delivered through a tube called an endotracheal tube, which is placed by the anaesthetist in the patient's windpipe (trachea). This at times can be unexpectedly difficult to do. A fiberoptic camera can be used to place this tube when difficulty arises or is anticipated. All anaesthetists need to be trained to be able to use a fiberoptic camera. Infrequent use of this technique can make it challenging for anaesthetists. The infrared red intubation system (IRRIS) may make the use of fiberoptic camera and the insertion of the breathing tube in airway less difficult and in doing so may decrease any potential harm to the patient. IRRIS is a small device which is placed on the throat. The device emits an infrared light which can be visualized inside the throat by a fibreoptic camera. It is thought to be a useful device in that it may aid fibreoptic intubation in both difficult and normal airways. This study will determine if the IRRIS device will make it easier for the anaesthetists to place the breathing tube in the windpipe and determine if this device should be used routinely by all anaesthetists.

Who can participate?
Patients over the age of 18 who require general anaesthesia and tracheal intubation for the surgical procedure can participate in the study.

What does the study involve?
Patients will be randomly assigned to receive the intubation process as normal or with the addition of the IRRIS device. The surgical procedure and follow-up will proceed as normal for all patients.

What are the possible benefits and risks of participating?
Potential benefits:
1. The IRRIS device may assist in identifying glottic opening in a quicker time so reducing the risk of potential hypoxia in a critical situation.
2. It may assist in increasing the confidence of using the fiberoptic scope among anaesthetists.
3. It may result in less trauma to the airway when the fiberoptic scope is being used.

Potential risk:
Trauma to the airway can occur as a result of the administration of general anaesthesia, this would be a risk with or without use of fiberoptic scope.

Where is the study run from?
Beaumont Hospital, Ireland

When is the study starting and how long is it expected to run for?
January to June 2019

Who is funding the study?
Beaumont Hospital, Ireland

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
001

Study information

Scientific Title
Does the infrared red intubation system (IRRIS) improve the fiberoptic intubation conditions? A randomized control trial

Study objectives
The Infrared Red Intubation System (IRRIS) improves the fibreoptic intubation conditions

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 31/12/2018, Beaumont Hospital Ethics (Medical and Research) Committee (Beaumont Hospital, Beaumont Road, Dublin 9, Ireland; 00 353 1 809 2680;beaumontethics@rcsi.com), ref: 18/56

Study design
Interventional single centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional file (ISRCTN88166769)

Health condition(s) or problem(s) studied
Difficult Intubation

Interventions
Patients were randomly allocated to intervention (intubation with IRRIS) and controls (intubation without IRRIS) (sealed envelope technique).

Both study arms received the same predefined standardised anaesthesia technique/ treatment ie fentanyl 2 µg/kg I.V induction was done with propofol target-controlled infusion (TCI) with target plasma concentration (CPT) between 4 to 6 mg/ml. After achieving BIS value between 40 to 60, all patients were manually ventilated with face mask 100% oxygen. Neuromuscular blocking agent (Vacronium 0.15 mg/kg I.V.) was administered after checking adequacy of mask ventilation.

In the intervention group, the IRRIS was attached to the patient's neck skin just beneath the laryngeal prominence (Adam's apple).
After the onset of neuromuscular block confirmed by using neuromuscular monitoring, fiberoptic bronchoscopy (FOB) was performed by the primary investigator. Theatre staff who was not involved in the study monitoring the time of FOB with a stopwatch.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Infrared intubation system (IRRIS)

Primary outcome measure
Time in seconds from when the point of the fiberoptic bronchoscope (FOB) is inserted in the mouth until it passes through the glottis, measured by using a stopwatch

Secondary outcome measures
1. Number of fiberoptic intubation attempts needed until successful intubation
2. Manoeuvres (head tilt, chin lift, jaw thrust and lingual traction) used to aid intubation

Overall study start date
15/07/2018

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Age >18 years old
2. Patients requiring general anaesthesia
3. Malampatti 1 and 2
4. ASA Physical Status Classification System 1and 2
5. Full capacity of giving informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
58

Total final enrolment
58

Key exclusion criteria
1. History of difficult intubation
2. Emergency surgery
3. BMI > 35 kg/ m2
4. Known anatomical anomalies of the airway
5. Pregnant

Date of first enrolment

01/01/2019

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Ireland

Study participating centre
Department of Anaesthesia
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Sponsor information

Organisation
Beaumont Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/043mzjj67

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beaumont Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/01/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/09/2019	No	Yes
Abstract results		01/07/2020	07/09/2021	No	No