

Infrared guided placement of a breathing tube before surgery

Submission date 06/08/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/09/2021	Condition category Surgery	<input type="checkbox"/> Individual participant data

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 fiberoptic camera. It is thought to be a useful device in that it may aid fiberoptic 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 1 and 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

Beaumont Hospital

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Sponsor information

Organisation

Beaumont Hospital

Sponsor details

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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