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A study to compare intubation conditions using the CTrach versus the Bonfils rigid fibrescope and CTrach intubating Laryngeal mask airway

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 02/09/2015	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0084186834

Study information

Scientific Title
A study to compare intubation conditions using the CTrach versus the Bonfils rigid fibrescope and CTrach intubating Laryngeal mask airway

Study objectives
Compare the airway management devices 'Bonfils' and 'CTrach' with respect to:
1. Time it takes to be placed it successfully in the throat
2. How quickly it helps to successfully place tube in windpipe for patients undergoing general anaesthesia for their operation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Intubation

Interventions
Patients are randomly selected to belong to either Bonfils group or CTrach group.

Procedure
In order to ensure that the conditions under which the study is conducted remains the same in all subjects, the following procedure will be followed at induction by the team managing the patient:
1. Pre-oxygenation for 3 minutes
2. Intravenous administration of Fentanyl 1-2 milligrams per kilogram patient weight to all patients

3. Either of two methods of induction of anesthesia with target controlled infusion (TCI) of Propofol to target 3-7 milligrams per ml, then maintenance target (TCI) 2.5-4 micrograms per ml with 50% oxygen and 50% air, or intravenous induction of bolus dose of propofol 2-3mg/ml and then anaesthesia maintained with 50% oxygen, 50% air and sevoflurane
4. Muscle relaxation with intravenous administration of Atracurium 0.5 mg/kg to all patients to aim for T0F with 1/4 for adequate muscle relaxation

Following oxygenation, adequate manual ventilation and assessment for adequate level of anaesthesia and relaxation, the following procedure will then follow:
1. Direct laryngoscopy and airway grading by experienced anaesthetist using Macintosh blade (in absence of anaesthetist to use trial device), and using the modified Cormack and Lehane laryngoscopy grading
2. Call back anaesthetist to insert trial device
3. Pick envelope to identify device
4. Start stop clock at beginning of insertion of device and stop it at time capnograph trace is seen
5. Device insertion after appropriate positioning of subjects head

Parameters to be monitored and recorded:
1. Ctrach group
2. Bonfils fibrescope group

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Which of the two devices will be successful and quicker in placing the device in throat and placing the tube in windpipe.

Secondary outcome measures
To compare the easiness and quality of the windpipe view obtained, to compare performance of consultants and registrars, to find out any relation between conventional scope grading and successful placement of tube in windpipe with both devices.

Overall study start date
29/09/2006

Completion date
01/10/2007

Eligibility

Key inclusion criteria
1. Age over 16 years
2. Elective surgery requiring endotracheal intubation
3. ASA status 1-3
4. Airway Mallampati grade 1-3
5. Competency to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
132

Key exclusion criteria
1. Morbid obesity (BMI > 35)
2. Pregnancy
3. Emergency surgery or inadequate starvation period
4. Gastro-oesophageal starvation period
5. Gastro-oesophageal reflux or hiatus hernia
6. Severe respiratory disease
7. Mental incapacity
8. Coagulation abnormalities
9. Oral surgery

Date of first enrolment
29/09/2006

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull Royal Infirmary
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Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium

Funder Name
Hull and East Yorkshire Hospital Trust

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration