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

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

## Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

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### Contact details

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## Additional identifiers

Protocol serial number 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

### Study type(s)

Treatment

### 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(s)

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

### Key secondary outcome(s))

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.

### 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** 

### Healthy volunteers allowed

No

### Age group

Adult

#### Sex

All

### 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

**United Kingdom** 

England

Study participating centre
Hull Royal Infirmary
Hull
United Kingdom
HU3 2JZ

# Sponsor information

### Organisation

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

# 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**

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes