

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

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<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/09/2015	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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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## 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

Hull

United Kingdom

HU3 2JZ

**Sponsor information****Organisation**

**Sponsor details**

The Department of Health  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

**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