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Comparison of three methods to facilitate orotracheal fibreoptic intubation

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/11/2022	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
N0265109342

Study information

Scientific Title
Comparison of three methods to facilitate orotracheal fibreoptic intubation

Study objectives
The object of the study is to determine whether laryngoscope-assisted fibreoptic intubation results in better airway clearance and a shorter intubation time than other methods of fibreoptic intubation, and also to determine if laryngoscope-assisted fibreoptic intubation reduces the cardiovascular response to intubation.

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)
Not specified

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
The investigators will carry out the normal bedside assessment of the airways of patients who require orotracheal intubation as part of their anaesthetic management. If a patient presents one of the criteria for difficult intubation {viz Mallampati class III or IV, thyromental distance <6.5 cm, interincisor distance between 3 and 5 cm, protruding upper teeth, small mouth or mandible or reduced neck mobility) he or she will be invited to take part in the trial. He or she will then be scheduled for an orotracheal fibreoptic intubation, since this is the most appropriate treatment when there is an increased risk of difficult intubation.

A normal general anaesthetic will be given comprising pre-oxygenation with 100% oxygen, induction with fentanyl (l mcg/kg) and propofol (2.5 mg/kg) and ventilation of the lungs with

oxygen, nitrous oxide and isoflurane (0.5% end-tidal) with the aid of a Guedel airway. After confirmation of easy ventilation of the lungs, atracurium (0.5 mg/kg) will be given and mask ventilation will be continued until muscular relaxation is complete.

Immediately before intubation, patients will be randomised to have one of three manoeuvres to facilitate fibreoptic intubation:
1. Jaw thrust while keeping the mouth open together with lingual traction applied using Duval's forceps.
2. The insertion of a Berman airway into the mouth.
3. The insertion of a Macintosh size 3 laryngoscope into the mouth, placing its tip into the vallecula and lifting the tongue anteriorly.

The following timings will be made on every patient:
1. Endoscopy time - the time for the fibrescope to pass from the lips to the carina and
2. Intubation time - the time from the fibrescope passing between the lips to the detection of carbon dioxide by the gas analyser.

Heart rate, non-invasive blood pressure and pulse oximetry will be measured and recorded at 1 min intervals throughout the procedure. After intubation, the patient's surgery will commence. The patients will be reviewed in the Recovery area and on the first postoperative day, on the general ward. The presence of pharyngeal or lingual discomfort will be assessed and graded as mild, moderate or severe.

If the oxygen saturation falls below 97% at any time, or the electrocardiogram (ECG) or blood pressure (BP) readings fall outside normal limits, or if the endoscopy is not completed with 60 s, or if there is any concern for the patient's safety, the study period will end and appropriate action will be taken to treat the patient and facilitate endotracheal intubation.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
07/05/2002

Completion date
07/03/2008

Eligibility

Key inclusion criteria
45 Patients will be recruited to the study.

1. Aged 16-65
2. American Society of Anesthesiologists (ASA) 1 or 2
3. Undergoing elective procedures requiring orotracheal intubation
4. Presenting one clinical sign predicting difficult intubation
5. Giving informed written consent.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
45

Key exclusion criteria
1. Cardiovascular or cerebrovascular disease
2. Diabetes
3. Autonomic neuropathy
4. Patients taking vasoactive drugs
5. Oesophageal reflux
6. Morbid obesity (Body Mass Index [BMI] >35)
7. Fixed flexion deformity of the spine
8. Patients known to be difficult intubations
9. Patients demonstrating multiple clinical signs which in combination strongly predict difficult intubation

Date of first enrolment
07/05/2002

Date of final enrolment
07/03/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Anaesthetics
Birmingham
United Kingdom
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Sponsor information

Organisation
Department of Health (UK)

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Richmond House
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

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

Results article	comparison of two methods of fibrescope-guided tracheal intubation	01/05/1991	Yes	No