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Comparison of the fibreoptic bronchoscope and bougie for tracheal 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
07/07/2009	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
N0176108553

Study information

Scientific Title

Study objectives
A gum elastic bougie is a semi rigid plastic covered rod which is commonly used to facilitate intubation with an endotracheal tube when difficulty arises as a result of an inadequate view of the larynx with a conventional laryngoscope. This involves 'blindly' placing the bougie in the trachea and guiding a trachael tube over it. Using a flexible fibreoptic bronchoscope has the advantages of allowing continuous visualisation of the airway. This study would compare the two techniques in anaesthetised patients.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Tracheal intubation

Interventions
Randomised trial. Randomisation will be achieved by selecting an envelope containing one of the two methods being studied for guiding the tube into the trachea. The patient will be anaesthetised and therefore unaware of which method is used. It will be impossible to blind the operator (ie the person placing the tube into the trachea) or the assistant (another anaesthetist holding the laryngoscope).

Intervention Type
Procedure/Surgery

Phase

Not Specified

Primary outcome measure
Time from visualisation of the vocal chords to passage of the tube into the trachea

Secondary outcome measures
The presence or absence of carbon dioxide in the expired gases as a measure of success or failure to pass the tube into the trachea

Overall study start date
11/04/2002

Completion date
31/07/2002

Eligibility

Key inclusion criteria
No less than 20 and no more than 30 patients in each group.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
11/04/2002

Date of final enrolment
31/07/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Anaesthetic Department
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results on comparison of single-use bougie with fibrescope	01/09/2003		Yes	No
Results article	results on comparison of single-use bougie with multiple-use bougie	01/09/2003		Yes	No