Comparison of the fibreoptic bronchoscope and bougie for tracheal intubation

Submission date	Recruitment status No longer recruiting	Prospectively registeredProtocol		
12/09/2003				
Registration date	Overall study status Completed	Statistical analysis plan		
12/09/2003		[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

Contact name

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Contact details

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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 summaryNot 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