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Leakage of fluid around the bronchial cuffs of double lumen endobronchial tubes (DLEBT)

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2009	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
N0054131773

Study information

Scientific Title

Study objectives
To determine the incidence of fluid leakage past the bronchial cuff of double lumen endobronchial tubes and to investigate the effectiveness of gel lubrication in reducing fluid leakage past the bronchial cuff. Demonstration by fibreoptic bronchoscopy of dye leakage past the bronchial cuff of double lumen endobronchial tubes placed in patients undergoing right sided thoracic procedure in the lateral position.

An aspiration rate of 44% has been shown in patients receiving unlubricated double lumen endobronchial tubes. We consider a clinically important reduction would be a reduction of 50%. Assuming a baseline aspiration rate of 44%, a sample size of 55 per group will provide a study of 80% power to detect this difference with a 5% chance of error (one tailed). 55 patients per group, plus 5 per group to allow for data corruption i.e. (55+5) x 2 = 120 patients in total.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised double blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Thoracic

Interventions
Adult patients scheduled to undergo a right thoracic procedure involving lung isolation will be randomly assigned to one of two groups.
One group will receive an unlubricated DLEBT and the other group will receive a DLEBT liberally lubricated with aqueous jelly. A left sided DLEBT will be used for a right sided procedure.
After placing the patients in a lateral position and confirming correct placement of the DLEBT

with a fibreoptic bronchoscope, both groups will receive 10 mg (1 ml) of methylthionium chloride (methylene blue) made up to 5 ml with normal saline placed above the bronchial cuff via an epidural catheter. At 30-minute intervals during the procedure and immediately prior to extubation, the endobronchial lumen will be aspirated and the aspirates examined by a blinded observer for staining. The same observer will then utilise a fibreoptic bronchoscope to examine the bronchial mucosa for blue staining.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Some patients develop acute respiratory distress syndrome (ARDS) after an uneventful pneumonectomy a condition termed post-pneumonectomy syndrome. The pathogenesis of this syndrome is poorly understood. An increase in hydrostatic pressure after lung removal is unlikely to be the sole cause in the majority of patients. Aspiration of infected material or gastric acid past the endobronchial cuff of an endobronchial tube may be a significant factor in the development of this syndrome. This study will demonstrate by fibreoptic bronchoscopy of dye leakage past the bronchial cuff of double lumen endobronchial tubes placed in patients undergoing right sided thoracic procedure in the lateral position.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2003

Completion date
31/05/2004

Eligibility

Key inclusion criteria
Adult patients undergoing thoracotomy or thoracoscopy.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
55 patients per group, plus 5 per group to allow for data corruption i.e. (55+5) x 2 = 120 patients in total.

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2003

Date of final enrolment
31/05/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthesia
Liverpool
United Kingdom
L14 3PE

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name
The Cardiothoracic Centre Liverpool 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

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	01/02/2006		Yes	No