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

Submission date 30/09/2004	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 07/01/2009	<b>Condition category</b> Surgery	<ul> <li>Individual participant data</li> </ul>

### Plain English summary of protocol

Not provided at time of registration

### **Contact information**

**Type(s)** Scientific

**Contact name** Dr P Sanjay

### Contact details

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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

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