A Prospective descriptive Pilot Trial to investigate tracheal reflux in the early post-operative period in patients undergoing thoracotomy for lung resection.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/09/2004		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2004	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
15/01/2009	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

Protocol serial number N0054128023

Study information

Scientific Title

Study objectives

A Randomised Controlled Trial to investigate tracheal reflux in the early postoperative period. Can acid reflux be reduced by the oral administration of a Proton Pump Inhibitor?

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Surgery: Thoracotomy

Interventions

A Prospective Randomised Double Blind Controlled Trial to investigate tracheal reflux in the early post-operative period. Consenting patients who are presenting for Thoracotomy for Lung resection under the care of two Thoracic surgeons. Patients after completion of surgery but prior to reversal of general anaesthetic, will have a 1.5 mm antimony pH probe inserted percutaneously under brochoscopic control into the trachea via the cricothyroid membrane. The device will then record and store pH every 5 seconds for the first 48 hour post-operatively, The data will be analysed for number and duration of aspiration episodes.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Study end points will be:

- 1. The number of episodes per hour as defined by a reversible decrease in pH to less than 6.5 and lasting at least 1 min
- 2. The fractional (%) time the pH is less than 6.5
- 3. The number of aspiration episodes lasting more than 5 min

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2003

Eligibility

Key inclusion criteria

50 patients undergoing thoracotomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

- 1. Patients who have thyroid goitre or pathology making thyrocricoid puncture difficult
- 2. Patients with a history of gastro-oesophageal reflux disease (GORD), Hiatus hernia or currently taking proton pump inhibitor (PPI)/antacid

Date of first enrolment

01/06/2003

Date of final enrolment

31/12/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Department of Cardiac Surgery

Liverpool United Kingdom L14 3PE

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

The Cardiothoracic Centre Liverpool NHS Trust (UK)

Results and Publications

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	01/05/2006		Yes	No