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

Submission date
30/09/2004

Registration date
30/09/2004

Last Edited
15/01/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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

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: 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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2003

Completion date
31/12/2003

Eligibility

Key inclusion criteria
50 patients undergoing thoracotomy

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
50

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

England

United Kingdom

Study participating centre
Department of Cardiac Surgery
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	01/05/2006		Yes	No