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Randomised trial comparing the use of suction with underwater seal versus only an underwater seal applied to chest drains following lung resection

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
15/02/2010

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
N0013145914

Study information

Scientific Title

Study objectives
Is there a difference between the two groups with respect to the three primary outcomes?

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)
Treatment

Participant information sheet

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

Interventions
Chest drains connected to an underwater seal are routinely left in the chest cavity (pleural space) following lung resections. They provide a one way escape route for any air that might leak from the surface of the lung and for any fluid that might collect in the chest cavity. This helps to maintain a negative pressure in the pleural cavity and facilitates lung expansion. We propose to compare the duration of air leak following lung resection between two groups of prospectively randomised patients one of which will have suction applied to the underwater seal. We will record the time to the last air leak and then determine any statistically significant difference (if any) between the two groups.

Randomisation will be into two groups: 1. chest drain connected to water seal only 2. chest drain connected to water seal and wall suction applied to the water seal at 3 kPa. Suction started in the recovery room immediately after the operation.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
1. Time to last bubble (air leak time)
2. Time to removal of drain
3. Time to discharge home

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2002

Completion date
01/06/2003

Eligibility

Key inclusion criteria
Cases eligible to be included in the trial: all lobectomies, all wedges, all lung biopsies, all operations of pneumothorax.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
300

Key exclusion criteria
Lung volume reduction surgery and pneumonectomies.

Date of first enrolment
01/06/2002

Date of final enrolment

01/06/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiothoracic Surgery
London
United Kingdom
SE17EH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Guy's and St. Thomas' NHS Foundation Trust (UK), Own Account

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	01/03/2005		Yes	No