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Mobile drainage with high suction versus mobile drainage with low suction.

Submission date
26/03/2018

Recruitment status
No longer recruiting

Registration date
13/04/2018

Overall study status
Completed

Last Edited
09/01/2020

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
When a section (lobe) of the lung has been removed by surgery from the chest, it is necessary to insert a chest drain (a plastic tube), so that air and fluid can be removed safely, and the remaining lung tissue can expand. Removing the air and fluid is routinely done by either applying suction, or passively with no suction.
The aim of this study is to see if there is a difference in the duration of air-leak when applying a high external suction to the chest drain versus a low external suction.

Who can participate?
Adults over the age of 18 years undergoing lung lobe surgery

What does the study involve?
Following surgery for removal of lobes of the lung participants are randomly assigned to one of two groups. Those in the first group receive low external suction whilst those in the second group receive high external suction, via a plastic tube (chest drain).Participants are followed up in the outpatient clinic two weeks after discharge from hospital.

What are the possible benefits and risks of participating?
Participants benefit from helping define new guidelines for postoperative care. There are no risks involved that are beyond what to expect after undergoing usual lung surgery.

Where is the study run from?
Odense University Hospital (Denmark)

When is the study starting and how long is it expected to run for?
March 2015 – April 2016

Who is funding the study?
Odense University Hospital (Denmark)

Who is the main contact?
Dr Marike Lijkendijk (Scientific)
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Thopaz 2.0

Study information

Scientific Title
The influence of suction on chest drain duration and fluid output after lobectomy using only electronic chest drainage systems – a randomized clinical trial

Study objectives
External suction on the chest drain after lobectomy has no influence on the duration of the chest drain.

The general theory is that application of high suction maintains alveo-pleural leakage and prolongs air-leak. On the other hand it is believed in the literature that external suction has to be applied in order for the residual lung to be fully expanded after lobectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics approval not required: Letter received 15/01/2015 from The Regional Ethics Committee (Southern Region of Denmark) deciding the study as a quality securing - or quality developing project, which falls out of the scope of the committees law given definition of a health scientific research project.

Study design
Single-center randomized study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

Health condition(s) or problem(s) studied
Pulmonary lobectomy

Interventions
Following pulmonary lobectomy (lower or upper lobes) patients are randomly assigned (1:1) by sequentially numbered, opaque, and sealed envelopes to one of two groups. Participants receive either low external suction (–5 cm H2O) or high external suction (–20 cm H2O) via a size 24 French silicone chest drain connected to an electronic drainage device. All other postoperative care is the same in both groups.
Treatment ends when the chest drains are removed. Both arms use a chest drainage removal algorithm; patients have to be well pain managed and mobilized. There is no upper limit on fluid output (providing it is serous and no chylous). Air leak is < 20 ml/min with no spikes for 6 hours or < 50 ml/min with no spikes for 12 hours.
Participants are followed up in the outpatient clinic two weeks after discharge from hospital.

Intervention Type
Procedure/Surgery

Primary outcome measure
Duration of air leakage is measured using the time of end of surgery and the time when the chest drain was removed (information from electronic patient charts).

Secondary outcome measures
1. Fluid output is measured by recording measurements from the drainage device cannister on the patient chart.
2. Length of stay is recorded from hospital records.
3. Re-insertion of chest drains (complications) is recorded using the information from the patient chart.

Overall study start date
01/03/2015

Completion date
30/04/2016

Eligibility

Key inclusion criteria
1. Admitted for lobectomy (by thoracotomy or video-assisted thoracoscopic surgery [VATS] as decided by the surgeon)
2. Aged over 18 years
3. Ability to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
106

Key exclusion criteria
1. Previous history of pulmonary or cardiac surgery
2. Expected difficulties with postoperative mobilization
3. Participation in concomitant research studies in our department in which a different chest drainage protocol could influence these results
4. Anticipation of a need for postoperative mechanical ventilation
5. Insertion of more than one chest drain
6. Bilobectomy or middle lobectomy

Date of first enrolment
03/03/2015

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
Denmark

Study participating centre
Department of Cardiothoracic and Vascular Surgery
Odense University Hospital
J. B. Winsløws Vej 4
Odense
Denmark
5000

Sponsor information

Organisation
Department of Cardiothoracic and Vascular Surgery

Sponsor details
Odense University Hospital
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5000

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ey0ed83

Funder(s)

Funder type
University/education

Funder Name
Odense Universitetshospital

Alternative Name(s)
Svendborg Sygehus, Odense University Hospital, OUH

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Denmark

Results and Publications

Publication and dissemination plan
The authors are intending to publish the air-leakage results on chest drain duration.

09/04/2018: Results presented at Society of Thoracic Surgeons 53rd Annual meeting 2017 (https://www.sts.org/sites/default/files/documents/53AM_AbstractBook.pdf)

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Marike Lijkendijk (elle.lijkendijk@rsyd.dk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018		Yes	No
Results article	results	01/06/2019	09/01/2020	Yes	No