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To determine whether the powered endopath stapler device reduces the incidence of prolonged air leak and duration of chest tube drainage after lung volume reduction surgery

Submission date
27/08/2014

Recruitment status
No longer recruiting

Registration date
04/12/2014

Overall study status
Completed

Last Edited
01/09/2020

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name used to refer to a number of progressive devastating and debilitating lung diseases, which includes chronic bronchitis, emphysema and chronic obstructive airways disease. People that have COPD typically feel breathless after physical activity, have a persistent cough with phlegm and suffer frequently from chest infections. There is no cure for the condition, but making lifestyle changes (such as stopping smoking) and taking medications (inhalers and/or tablets) can alleviate symptoms. Pulmonary rehabilitation, a programme of physical exercise and education, can also help people manage their condition and lead to improvements in health. However, in the most severe cases, the only options are often a lung transplant or lung-volume-reduction surgery (LVRS). The use of lung transplantation as a treatment is limited due to the shortage of donors and unsatisfactory results in elderly people suffering from other diseases at the same time. LVRS involves removing the most badly affected part of the lungs in order to improve function. Studies have shown that it reduces shortness of breath and improves lung function and quality of life in patients with severe pulmonary emphysema. One of the most common complications of the procedure, however, is air leakage, which is caused by air leaking into the chest cavity. Patients with severe emphysema are at high risk of developing prolonged air leak after the surgery. Prolonged air leak is defined as air leak lasting more than 7 days after the surgery. It causes increased medical and non-medical costs, complications associated with pain from the presence of chest tubes, immobilization, risk of infection and may even lead to further surgery. It therefore represents a major limiting factor for discharge from the hospital. Here, we have set up a study to test new techniques to avoid or to reduce the occurrence of prolonged air leak after LVRS.

Who can participate?
Adults (aged at least 18) with severe pulmonary emphysema and about to undergo LVRS.

What does the study involve?
Participants are randomly allocated to undergo LVRS with the use of either the Echelon FLEX™

Powered ENDOPATH® Stapler or Echelon FLEX™ ENDOPATH® Stapler. After surgery, we look at the data from both groups and compare the amount of air leak, duration of chest tube drainage and how successful the surgery is at treating the condition.

What are the possible benefits and risks of participating?
We hope that the technical advantage of powered stapler may help people who have LVRS using this technique with their severe emphysema symptoms. We expect that the patients will be discharged from hospital sooner and transferred earlier to a rehabilitation clinic.

Where is the study run from?
University Hospital of Basel, Division of Thoracic Surgery (Switzerland)

When is the study starting and how long is it expected to run for?
July 2014 to July 2015

Who is funding the study?
University Hospital of Basel, Division of Thoracic Surgery (Switzerland)

Who is the main contact?
Katarzyna Furrer
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Powered endopath stapler device reduces the incidence of prolonged air leak and duration of chest tube drainage after lung volume reduction surgery: A prospective randomized blinded study

Acronym
N/A

Study objectives
With powered stapler technic (Echelon FLEX™ Powered ENDOPATH® Stapler) in treatment group, we expect a further decrease of the air leak, duration of chest tube drainage and enhancement of the outcome in comparison to control group with non-powered stapler technic. (Echelon FLEX™ ENDOPATH® Stapler).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Swiss Ethics Committee Norwest- and Central Switzerland; 02/07/2014; Ref. EKNZ 2014-074

Study design
One-year prospective randomized blinded study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lung emphysema, chronic obstructive pulmonary disease

Interventions
Bilateral lung-volume-reduction-surgery (LVRS) by video-assisted thoracic surgery (VATS) with use of powered versus non-powered Endopath stapler from Echelon for left or right side of the lung. Before LVRS this side was randomly assigned in the operating room to the control (non-powered Echelon) or the treatment group (powered Echelon) by opening of a sealed envelope.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Incidence and volume of air leaks
2. Duration of chest tube drainage of the each side

Key secondary outcome(s))
1. Duration and volume of air leak postoperative as well as twice a day, each morning and each afternoon until removal of the chest tubes
2. Operative time, and postoperative complications grade e.g. necessity of reoperation, hospitalisations time

Completion date
03/07/2015

Eligibility

Key inclusion criteria
1. Adult patients with non-bullous pulmonary emphysema were included when they were severely symptomatic despite optimal medical therapy
2. Had severe air flow obstruction (forced expiratory volume in 1 second (FEV1) of 40% of predicted value)
3. Had pulmonary hyperinflation (residual volume (RV) of 200% of predicted value, RV/total lung capacity of 0.60)
4. Minimum age of 18 years
5. Able to consent and indication for bilateral LVRS with a signed informant consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Patients with bullous pulmonary emphysema
2. Severely impaired carbon dioxide diffusing capacity (20% of predicted value)
3. Significant coronary artery disease
4. Under age of 18 years
5. Persons unable to consent and without a signed informant consent

Date of first enrolment
02/07/2014

Date of final enrolment
03/07/2015

Locations

Countries of recruitment
Switzerland

Study participating centre
Division of Thoracic Surgery
University Hospital of Basel
Basel
Switzerland
CH-4031

Sponsor information

Organisation
University Hospital Basel

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
University/education

Funder Name
University Hospital of Basel (Switzerland) - Department of Thoracic Surgery

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes