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Digital air leaks evaluation after pulmonary resections

Submission date	Recruitment status	[ ] Prospectively registered
20/11/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/02/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/02/2016	Respiratory	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Long-term conditions which affect the lungs (chronic lung disease) and the airways are a growing problem worldwide. People with CLD are likely to experience breathlessness and chest pain, especially when exerting themselves, and so sufferers tend to avoid exercise. This can lead to their lung conditions getting worse, causing disability that is both a source of suffering and strain on the health services. Medication can be used to help improve the symptoms of CLD however it does not stop the disease from getting worse in the long term. Lung resection is an operation in which all or part of the lung is removed. Following this type of surgery, it is very important to maintain the correct pressure in the chest so that the lungs can inflate properly. This is done by placing tubes into the space around the lungs in the chest (pleural cavity) so that any air, blood, fluid or pus can drain out of the chest (chest drainage). Traditionally, the tube is attached to a system where the air or fluid “bubbles” through water inside (underwater seal). This underwater seal acts as a one-way valve and prevents the air or fluid from going back up into the pleural space. In recent years, some companies have developed chest drainage systems that contain a digital air leak meter. The aim of this study is to look at the performance of a digital chest drainage system compared to an underwater seal chest drainage system in patients who have had a pulmonary resection.

Who can participate?
Adults who have undergone a pulmonary resection.

What does the study involve?
Participants are randomly allocated to one of two groups. Following their lung resection surgery, participants in both groups have chest tubes (drains) placed into the pleural cavity, which are connected to an underwater seal drainage system. For participants in the first group (study group), the chest drainage system is connected to a digital device to monitor any air leaks. For participants in the second group, the drainage system is used alone. After the surgery, participants have a medical examination and chest x-ray every two days until they are discharged from hospital. The length of time it takes between the surgery and discharge from hospital is recorded in days for both groups.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico (Italy)

When is the study starting and how long is it expected to run for?
September 2010 to December 2011

Who is funding the study?
REDAX S.r.l. (Italy)

Who is the main contact?
Professor Mario Nosotti
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Digital versus analogic chest drainage in pulmonary resection

Acronym
DigiLeaks

Study objectives
Digital air leak evaluation should have more advantages in reducing chest drain and hospital stay after pulmonary resections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Foundation IRCCS Ospedale Maggiore Policlinico of Milan Ca'Granda (Comitato Etico Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico di Milano), 18/05/, ref: 1065

Study design
Single-centre prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

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

Interventions
Patients are randomly allocated to one of two groups by electronic calculator.

Study group: Following lung resection surgery (pulmonary lobectomy or segmentectomy), chest tubes are connected to common water seal drainage. The drainage system is also connected to a digital device for evaluation of air leaks.

Control group: Following lung resection surgery (pulmonary lobectomy or segmentectomy), chest tubes are connected to common water seal drainage only.

Follow up for all participants consists of a daily medical examination as well as a chest x-ray every two days until discharge from hospital. One week after discharge, participants return for a repeat medical examination and chest ray. The medical examination is then repeated every 30 days until the study end (4 months after surgery).

Intervention Type
Device

Primary outcome measure
Chest tube permanence is measured by recording the days from the operation to the removal.

Secondary outcome measures
Postoperative hospital stay measured in days from time of operation until time of discharge.

Overall study start date
01/09/2010

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Pulmonary resection
3. Informed consent obtained

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
98

Key exclusion criteria
1. Patients requiring pneumonectomy
2. Patients requiring surgery for pneumothorax
3. FEV1%<70%
4. FEV1/FVC<70%
5. Hepatic or renal insufficiency
6. Systemica autoimmune diseases

7. Chronic corticosteroids treatment
8. Patients requiring lung volume reduction surgery
9. Patients requiring sleeve lobectomy

Date of first enrolment
01/09/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico
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Sponsor information

Organisation
REDAX S.r.l.

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Sponsor type
Industry

ROR
https://ror.org/03c0asn85

Funder(s)

Funder type
Industry

Funder Name
REDAX S.r.l.

Results and Publications

Publication and dissemination plan
Planned publication in a Surgical Journal (i.e. European Journal Cardio-Thoracic Surgery).

Intention to publish date
30/11/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository