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A newly developed chest drainage unit with an integrated CO2 detector

Submission date	Recruitment status	[ ] Prospectively registered
13/06/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/07/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/07/2019	Surgery	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Air leakage following thoracic surgery is common and leads to increased morbidity, costs and length of hospitalization. An air leak not caused by an alveolo-pleural fistulae (true air leak) is termed false air leak. Unrecognized false air leakage results in unnecessarily prolonged chest tube duration, costs and risks of complications. The correct interpretation of whether the air leakage is true or false is consequently paramount to correct decision making and timing of safe chest drain removal.

Unfortunately, both traditional water seal and electronic drainage systems cannot distinguish false air leakage from true air leakage. The aim of the present study was to test a new chest drainage unit, where a CO2-sensitive colour indicator is integrated into the chest drainage unit to distinguish true air leakage form false air leakage.

Who can participate?
All of the patients that are eligible for surgery are informed before surgery by a doctor in written form and oral. All patients signing an informed consent form are included in the pilot study.

What does the study involve?
During a period of three weeks, 14 consecutive adult male and woman are operated in Dep of Cardiothoracic surgery, OUH, Denmark with open surgery and VATS surgery with minor resections of the lung (subsegmental resections) and major resections of the lung (lobectomies and bilobectomies). All patients are operated in general anaesthesia with double lumen intubation.

After the pilot study using only the chest drainage unit with CO2 indicator for all patients, the trial will continue with measurement of intrathoracic pressure with a pressure indicator inserted in the thoracic cavity. Pressure measurement will be performed for patients with the new chest drainage, a standard chest drainage unit and a digital chest drainage unit.

What are the possible benefits and risks of participating?
There are no direct benefits for the persons taking part in the trial. The risks are the same as risks involved in having a chest tube in general (wound infection, pain).

Where is the study run from?
Odense University Hospital

When is the study starting and how long is it expected to run for?
April 2019 to May 2020

Who is funding the study?
The study is funded by the Odense University Hospital and the Southern Denmark University Research & Innovation Organisation. The 14 chest drainage units are delivered without payment from the manufacturer Sinapi Biomedicals.

Who is the main contact?
Consultant Jens Eckardt
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Acadre 17/33766

Study information

Scientific Title
A newly developed chest drainage unit with an integrated CO2 detector: an observational case-control study

Acronym
N/A

Study objectives
Postoperative observed air leakage does not always originate from parenchymal defects but may arise from defects in the chest drainage unit, connections or reverse airflow in water seals. The aim of the present study was to test a new invention in the clinic, where a CO2-sensitive colour indicator is integrated in the chest drainage unit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics board for the region of southern Denmark decided that there was no need for approval from an ethics committee.

Study design
pilot feasibility, observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Lung surgery, either open surgery or vats (video-assisted thoracoscopic surgery)

Interventions
All persons included in the trial according to the inclusion criteria are operated according to the recommendations in the department. Surgery is performed in general anesthesia and after the resection of the lung tissue, a chest tube (silicone tube) is inserted. In the trial involving intrathoracic pressure measurement, an additional tube (plastic tube) is inserted (thickness 2-4 millimeter). When there is no air leakage from the lung tissue both tubes are removed followed by a chest x-ray after 2-4 hours. The operated persons are discharged from the hospital according to the recommendations in the department. The trial does not involve any follow-up.

All information is collected from patient records. The trial run from the day of surgery until the person has been discharged from the hospital.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
1. The complication rate is measured by collecting data from patient records.
2. Chest tube reinsertion rate is measured by collecting data from patient records.
3. The length of chest tube duration is measured by collecting data from patient records.
4. The length of stay is measured using by collecting data from patient records.

Secondary outcome measures
The number of patients with false air leakage versus true air leakage is measured by collecting data from patient records.

Overall study start date
01/07/2018

Completion date
01/06/2020

Eligibility

Key inclusion criteria
1. Aged 18 to 90 years.
2. Open or vats procedures with non-small lung cancer or undiagnosed lesions.
3. Lobectomies, bilobectomies or diagnostic resections of lung tissue.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
Patients who cannot give informed consent.

Date of first enrolment
01/04/2019

Date of final enrolment
01/05/2019

Locations

Countries of recruitment
Denmark

Study participating centre
Odense University Hospital, Dep. Cardiothoracic surgery
JB Winsløw 4
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Denmark
5000

Sponsor information

Organisation
Odense University Hospital, Dep of Cardiothoracic surgery

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
www.ouh.dk

ROR
https://ror.org/00ey0ed83

Funder(s)

Funder type

University/education

Funder Name
Odense University Hospital

Funder Name
Southern Denmark University Research & Innovation Organisation

Results and Publications

Publication and dissemination plan
Planned publication in an internationally recognized journal focused on Cardiothoracic Surgery.

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other