Trial Description

Title

Point-of-Care Ultrasound Diagnostics of the Lung - New Areas of Application in Anaesthesiology and Thoracic Surgery

Study 2: Use of ultrasound for postoperative controls after lung resection surgery

Trial Acronym

SONOR

URL of the trial

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Brief Summary in Lay Language

Patients undergoing thoracic surgery receive thoracic drainage during the operation, a tube that transports air and secretions from the chest immediately after the operation and during the healing phase. By means of the chest tube it is possible to determine whether there is still a small air leakage in the lungs. On the first postoperative day and after removal of the chest tube, an x-ray is taken as standard to check whether the lung has fully expanded. There are hints that the ultrasound examination of the chest could be at least as accurate as the standard method. In contrast to x-rays, however, ultrasound is less harmful to the body because no ionising radiation is used.
In patients undergoing thoracic surgery, we would like to use ultrasound in addition to monitoring the lungs in the post-anaesthesia care unit and x-ray and compare whether the ultrasound is equivalent. The ultrasound examination has no known side effects.

Brief Summary in Scientific Language

A reliable sonographic evaluation of pulmonary structures was considered impossible for a long time, since the sound waves in air-filled rooms and tissues are not transmitted and thus deeper structures are not included in the image. However, it has been shown that the representation of pleural interfaces, parenchymatous structures and the resulting sonographic artefacts and phenomena allow a reliable diagnosis. The first ultrasound diagnosis of a pneumothorax was described in 1986 in veterinary medicine. Subsequently, pulmonary ultrasound was also introduced in human medicine and has become increasingly important. However, the establishment as bed-side routine diagnostics was only made possible by the development of smaller portable ultrasound devices. At present, ultrasound in the intensive care unit is already replacing the classical radiographs of the thorax for numerous problems (e.g. pneumothorax, pleural effusion, infiltrations). These developments are based on the high sensitivity and specificity of sonography for the detection of pleural and pulmonary pathologies, the comparatively steep learning curve, the ubiquitous availability and the avoidance of ionizing radiation and intra-hospital transports. Essential pathologies such as pulmonary oedema, pleural effusion and pneumothorax can be detected by the lung gliding (breath-shifting gliding of the

visceral at the parietal pleura), the A-lines (an artefact parallel to the pleural line) and the B-lines (artefacts parallel to the sound direction) in the B- and M-mode of the ultrasound device. The determination of the so-called "lung point" (point of sonographic reunification of the visceral and parietal pleura after air-induced separation by a pneumothorax) allows the semiquantification of a pneumothorax. In contrast to intensive care and emergency medicine, pulmonary ultrasound is currently rarely used in anaesthesia and in the normal surgical ward, although thoracic surgery in particular offers a wide range of possible applications. The interdisciplinary evaluation of pulmonary ultrasound in various areas of thoracic anaesthesia and thoracic surgery to reduce the resource-intensive and potentially harmful equipment routine diagnostics is the subject of this research project. The benefit of lung sonography is to be examined for monitoring the course of postoperative pathologies.

Do you plan to share individual participant data with other researchers?

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00014557**
- Date of Registration in DRKS: **2018/09/06**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **38/2018 , Ethik-Kommission der Universität Witten/Herdecke**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1219-6898**

Health condition or Problem studied

- ICD10: **J95.80 - [generalization J95.8: Other postprocedural respiratory disorders]**

Interventions/Observational Groups

- Arm 1: **Patients with lung resection thoracic surgery receive a standard x-ray on the first postoperative day and after removal of the chest tube. During the study, patients will also receive an additional thoracic ultrasound at three**

times (in the recovery room, on the first postoperative day and after removal of the chest tube). Sonography and X-rays are compared.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Sensitivity of thoracic ultrasound for postoperative pneumothorax after removal of the chest tube, controlled by X-ray.

Secondary Outcome

Specificity of pulmonary sonography for a pneumothorax after removal of chest tube after lung resection thoracic surgery compared to conventional chest x-ray.
Sensitivity and specificity of lung sonography for a pneumothorax 2 hours after lung resection thoracic surgery in the recovery room, measured at the reference of the chest tube (air leakage).
Sensitivity and specificity of pulmonary sonography for a pneumothorax on the first day after lung resecting surgery
Detection of pleural effusions
Detection of parenchymal changes
examination duration
Real or potential damages of the diagnostics are quantified (radiation dose)
Differences in the assessment of the relevance of a detected pneumothorax
Comparison of resources used

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Lungenklinik Köln-Merheim, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/08/31**
- Target Sample Size: **121**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

lung resecting thoracic surgery
capable patient
consent

Exclusion criteria

- Persons who are dependent on or employed by the sponsor or investigator
- Accommodation in an institution due to a court or official order
- Disable patient who is unable to understand the nature, meaning and scope of the study
- Pregnancy and lactation

Addresses

- **Primary Sponsor**

  Kliniken der Stadt Köln gGmbH, Standort Merheim
  Ostmerheimerstraße 200
  51109 Köln
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

  Klinikum der Universität Witten/Herdecke - KölnKlinik für Anästhesiologie und operative Intensivmedizin
  Mr. Dr. Jérôme Défosse

Contact for Scientific Queries

Klinikum der Universität Witten/Herdecke - KölnKlinik für Anästhesiologie und operative Intensivmedizin
Mr. Dr. Jérôme Défosse
Ostmerheimer Straße 200
51109 Köln
Germany

Telephone: **+49 221 8907 - 3863**
Fax: **+49 221 8907 - 3868**
E-mail: **defossej at kliniken-koeln.de**
URL: **www.kliniken-koeln.de**

- **Contact for Public Queries**

Klinikum der Universität Witten/Herdecke - KölnKlinik für Anästhesiologie und operative Intensivmedizin
Mr. Dr. Jérôme Défosse
Ostmerheimer Straße 200
51109 Köln
Germany

Telephone: **+49 221 8907 - 3863**
Fax: **+49 221 8907 - 3868**
E-mail: **defossej at kliniken-koeln.de**
URL: **www.kliniken-koeln.de**

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

Private Universität Witten/Herdecke Interne Forschungsförderung
Alfred-Herrhausen-Straße 50
58448 Witten
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/04/30**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*