

## Trial Description

### Title

**Sonography versus roentgenogram after thoracic surgery**

### Trial Acronym

**SONOR2**

### URL of the trial

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### Brief Summary in Lay Language

After chest surgery, radiographs are taken regularly to determine whether the lungs are fully extended, whether there is fluid retention in the chest, and whether there is inflammation or bleeding. Of particular interest is whether there is a pneumothorax, i.e. whether air has escaped from the lungs. There are indications that a simple ultrasound examination could be as helpful as X-rays. The advantage of ultrasound is that it does not require radiation. In patients with lung surgery, we want to perform ultrasound in addition to X-rays and compare the accuracy of the two examination methods.

### Brief Summary in Scientific Language

Transthoracic lung sonography has developed into a simple, fast, radiation-free and versatile alternative to X-rays in many areas. It is, for example, suitable for the emergency examination of critically ill patients, for the detection of spontaneous, traumatic or interventional pneumothorax, for therapy monitoring of pulmonary edema or pneumonia. In these applications it is superior to X-rays in diagnostic (sensitivity, negative predictive value) and practical terms (examination of lying patients, independence from radiological personnel, ubiquitous and immediately available). However, as the list suggests, most of the examinations come from internal intensive care medicine and traumatology. There is very little data from thoracic surgery that would benefit from a radiation-free alternative, especially through routine postoperative X-ray thoracic controls. The previous studies including our own SONOR study are very heterogeneous with sensitivities between 18% and 100%. Possible causes are unsuitable technology (modern ultrasound equipment filters the decisive artifacts and reduces the significance of pleuropulmonary ultrasound), inadequate methodology, ambiguity about the optimal examination position and sometimes very restrictive "academic" selection criteria that cannot be transferred to daily routine.

A major interest after thoracic surgery is the residual pneumothorax, which determines the duration of the drainage treatment. SONOR had shown a sensitivity of 32% for all pneumothoraces, including the smallest, increasing to 100% for  $\geq 3$ cm large pneumothorax. In fact, these are the relevant Pneumothoraces, which usually require re-drainage. However, the prevalence of Pneumothorax naturally decreases with its size, so that the data from SONOR for Pneumothoraces  $\geq 1$ cm show insufficient statistical power. In addition, we have learned methodological subtleties with which we expect a higher sensitivity per se in the future. The present SONOR-2 study is therefore intended to evaluate the

**test parameters with improved methodology and an increased number of cases.**

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

**No**

**Description IPD sharing plan**

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## Organizational Data

- DRKS-ID: **DRKS00020216**
- Date of Registration in DRKS: **2019/12/03**
- 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.: **140/2019 , Ethik-Kommission der Universität Witten/Herdecke**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1244-8088**

## Health condition or Problem studied

- ICD10: **J93.8 - Other pneumothorax**
- ICD10: **J90 - Pleural effusion, not elsewhere classified**

## Interventions/Observational Groups

- Arm 1: **Patients with an indication for lung or chest wall resection surgery except for pneumonectomy receive a systematic ultrasound examination of the thorax on the first postoperative day and after removal of the chest tube in addition to the standard X-ray image. The results of both types of examination are compared.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
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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 lung ultrasound compared with chest X-ray for a residual pneumothorax of at least 1.5cm size (apex-to-cupola in upright chest roentgenogram) after removing the chest tube**

### Secondary Outcome

**Specificity, predictive values, likelihood ratios, diagnostic odd's ratio, test parameters for other pneumothorax cut-off values, test parameters for other pleural or pulmonary pathologies, all compared with chest roentgenogram**

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

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

### Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2020/12/07**
- Target Sample Size: **300**
- 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 or chest wall resection including visceral decortication, pulmotomy and bronchotomy, except pneumonectomy**

### Exclusion criteria

**pregnancy**

### Addresses

#### ■ Primary Sponsor

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### Sources of Monetary or Material Support

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

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### Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]\*

### 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.