Trial Description

Title

Multispectral Optoacoustic Tomography for the ex vivo evaluation of pleural effusions

Trial Acronym

MSOT_pleural effusion ex vivo

URL of the trial

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Brief Summary in Lay Language

In patients with a pathologic accumulation of fluid within their pleural cavity (the space between the lung and the chest wall), a thoracocentesis (aspiration of the fluid) is performed as a therapeutic relief and to further analyze the fluid in order to define the underlying disease (diagnosis). The analysis of this fluid is performed in specialized laboratories in order to measure protein content, hemoglobin content and other parameters.
Ultrasound is an important and highly sensitive technique to confirm the presence of fluid in the pleural cavity and has an important advantage over e.g. computed tomography (CT): it operates without ionizing radiation (X-rays). In some cases it also allows for a rough characterization of the internal structure of the pleural fluid, but more often the results are not conclusive and a detailed analysis of protein and hemoglobin content is not possible.

In this study, a new and highly sensitive technique for the identification and quantification of pleural fluid components will be tested by measuring surplus fluid that is left over after all material for regular diagnostic tests has been taken.

The technique is called multispectral optoacoustic tomography (MSOT) and it uses an acoustic source with an additional laser to analyze the pleural fluid. As the measurement is exclusively performed on ex vivo pleural fluid (meaning on the fluid after the removal), there is no risk for participating patients. We will compare our measurement results with the parameters obtained during routine (laboratory) analysis. Our device is not a licensed medical device and has no CE certificate.

Prospectively, we hope to enable clinicians to determine the configuration of pleural fluid even before thoracocentesis (aspiration).

Brief Summary in Scientific Language

The proposed study is designed as a pilot study to evaluate the usefulness of MSOT for the evaluation of pleural effusions of different pathogenetic origins using ex vivo samples.
As the current gold standard for the detailed evaluation of pleural effusions requires an invasive procedure, new non-invasive methods that allow for fast, quantitative, and accurate measurements are urgently needed. In comparison to

other techniques, MSOT provides relevant advantages such as non-invasive imaging and highly sensitive direct detection of specific molecules such as proteins and hemoglobin.
Protein content is an important item of the established Light's criteria for the distinction of transudate and exudate in pleural effusions. In this current first step, we aim to evaluate the feasibility of the MSOT-based measurement of the protein content of pleural effusions by performing ex vivo measurements on pleural effusion samples of both subgroups.
The non-invasive detection of blood (hemoglobin) would for example also allow for the fast diagnostic distinction between residual pleural effusion and iatrogenic bleeding in patients post-thoracocentesis. We therefore aim to evaluate the capability of the MSOT technology to ex vivo measure hemoglobin in samples of hemorrhagic pleural effusions.
As there is no universally accepted consensus definition of the term "hemothorax" beyond that it is a "hemorrhagic pleural effusion", we will use the judgment of the experienced clinician performing the thoracocentesis to identify patients with gross hemorrhagic effusions to ensure a sufficient number of samples with relevant hemoglobin content instead of using a particular hemoglobin concentration as cut-off for our group defining criterion.
The proposed study incorporates no risk for patients and might provide relevant data for more in depth analysis of MSOT for lung disease.

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: **DRKS00016715**
- Date of Registration in DRKS: **2019/02/13**
- 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.: **421_18 B , Ethik-Kommission der Friedrich-Alexander-Universität Erlangen-Nürnberg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1228-4379**

Health condition or Problem studied

- ICD10: **J90 - Pleural effusion, not elsewhere classified**
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ICD10: **J91 - Pleural effusion in conditions classified elsewhere**

Interventions/Observational Groups

- Arm 1: **Pleural fluid from patients with transudate will be analyzed after removal by thoracocentesis using a onetime MSOT (multispectral optoacoustic tomography) ex vivo measurement. The inclusion of patients will occur after the completion of the thoracocentesis. Therefore, the aspiration itself does not constitute a study measure.**
- Arm 2: **Pleural fluid from patients with exudate will be analyzed after removal by thoracocentesis using a onetime MSOT (multispectral optoacoustic tomography) ex vivo measurement. The inclusion of patients will occur after the completion of the thoracocentesis. Therefore, the aspiration itself does not constitute a study measure.**
- Arm 3: **Pleural fluid from patients with hemorrhagic effusion will be analyzed after removal by thoracocentesis using a onetime MSOT (multispectral optoacoustic tomography) ex vivo measurement. The inclusion of patients will occur after the completion of the thoracocentesis. Therefore, the aspiration itself does not constitute a study measure.**

Characteristics

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

Primary Outcome

Comparison of MSOT (multispectral optoacoustic tomography) results for ex vivo pleural fluid of the groups “transudate”, “exudate”, and “hemorrhagic effusion”. The MSOT measurement after study inclusion will be performed at “Medizinische Klinik 1, Ulmenweg 18, 90154 Erlangen“.

Secondary Outcome

If available, comparison of lab parameters and other diagnostic results with the MSOT (multispectral optoacoustic tomography) results after completion of the MSOT measurement.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Erlangen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/05/08**
- Target Sample Size: **45**
- 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

**Already completed thoracocentesis;
minimum age of 18 years**

Exclusion criteria

**Minors (patients under the age of 18 years);
pregnant patients**

Addresses

- **Primary Sponsor**

  Universitätsklinikum Erlangen
  Maximiliansplatz 2
  91054 Erlangen
  Germany

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■ **Contact for Scientific Queries**

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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.*