

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Remodelling of lung architecture

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

With the aid of this project we will investigate the contribution of cells and cellular products in the remodelling of lung architecture in various diseases such as COPD, sarcoidosis, asthma bronchiale and idiopathic pulmonary fibrosis. The aim of this project is the better understanding of pathomechanisms in these diseases and the definition of potential biomarkers. From our findings, we are going to develop new therapeutic strategies.

Brief Summary in Scientific Language

In this study we will collect bronchoalveolar lavage, transbronchial biopsies, PBMC and serum from patients with COPD, asthma bronchiale, idiopathic pulmonary fibrosis and sarcoidosis. From BAL, peripheral blood and transbronchial biopsies we are going to isolate different cell types. Studies with these isolated cells as well as with BAL-fluids and serum will evaluate mechanisms, which are involved in the remodelling of lung architecture. The aim of this is to define new biomarkers of remodelling and new disease concepts, which will lead to new therapeutical strategies.

Organizational Data

- DRKS-ID: **DRKS00000620**
- Date of Registration in DRKS: **2010/11/25**
- Date of Registration in Partner Registry or other Primary Registry: **2008/01/30**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **231/03** , **Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

Secondary IDs

- Partner Registry-ID: **UKF001442 (Register klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied

- ICD10: **J84 - Other interstitial pulmonary diseases**
- ICD10: **J44 - Other chronic obstructive pulmonary disease**
- ICD10: **J84.1 - Other interstitial pulmonary diseases with fibrosis**
- ICD10: **D86.0 - Sarcoidosis of lung**
- ICD10: **J45 - Asthma**

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Evaluation of biomarkers and pathomechanisms in lung diseases with remodelling of the lung architecture.

Secondary Outcome

Survival, pulmonary function test parameter, cytokin levels, biomarker levels

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2003/12/11**
- Target Sample Size: **150**
- 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

Healthy volunteers, patients with COPD, asthma bronchiale, sarcoidosis and idiopathic pulmonary fibrosis, who will undergo a routine bronchoscopy.

Exclusion criteria

Infection, cancer

Addresses

- **Primary Sponsor**

**Abteilung für Pneumologie
Universitätsklinikum Freiburg
Antje Prasse
Kilianstrasse 5
79106 Freiburg
Germany**

Primary Sponsor

**Abteilung für Pneumologie
Universitätsklinikum Freiburg
Antje Prasse
Kilianstrasse 5
79106 Freiburg
Germany**

Telephone: **0761 2703720**

Fax: **0761 2703704**

E-mail: **antje.prasse at uniklinik-freiburg.de**

URL: [---]*

■ **Contact for Scientific Queries**

**Abteilung für Pneumologie
Universitätsklinikum Freiburg
PD Dr. med. Antje Prasse
Kilianstrasse 5
79106 Freiburg
Germany**

Telephone: **0761 2703720**

Fax: **0761 2703704**

E-mail: **antje.prasse at uniklinik-freiburg.de**

URL: [---]*

■ **Contact for Public Queries**

**Universitätsklinikum Freiburg
Abteilung Innere Medizin V - Pneumologie
Ms. PD Dr. med. Antje Prasse
Hugstetter Straße 55
79106 Freiburg
Germany**

Telephone: **+49 761 270-3720**

Fax: [---]*

E-mail: **antje.prasse at uniklinik-freiburg.de**

URL: **<http://www.uniklinik-freiburg.de/pneumologie/live/index.html>**

Sources of Monetary or Material Support

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

**Abteilung für Pneumologie
Universitätsklinikum Freiburg
Ms. PD Dr. med. Antje Prasse
Kilianstrasse 5
79106 Freiburg**

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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.