

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

Trial Description

Title

Imaging Disease Progression in COPD

Trial Acronym

MR-COPD II

URL of the trial

[---]*

Brief Summary in Lay Language

In this follow-up trial, MRI and CT images of the lung will be acquired prospectively in a subcohort of 370 patients, three years after they successfully participated in the first COSYCONET subtrial with CT and MRI (“MR-COPD I”).

The objective is to obtain longitudinal data from a well-characterized collective of COPD (Chronic Obstructive Pulmonary Disease) patients in order to determine the diagnostic value of CT and functional MRI for the monitoring of disease progression and to evaluate the prognostic value of image-based biomarkers.

Brief Summary in Scientific Language

The primary goal of this trial is to identify and evaluate the diagnostic value of suitable image-based biomarkers to improve the prognosis of disease progression of COPD in comparison to clinical tests. In conjunction with the data obtained in MR-COPDI, quantitative software-based analysis of CT (density-based evaluation of air-trapping, airway- and emphysema parameters, e.g. PI10, LAA%, E/I-MLD) and perfusion MRI (e.g. pulmonary blood volume (PBV) and pulmonary blood flow (PBF)) will be available for a three year interval. These will be correlated with clinical parameters measured at the time of the second imaging acquisition and the again following three years. A progression of the disease is defined as an increase of the multidimensional 10-point BODE index by at least one point.

Organizational Data

- DRKS-ID: **DRKS00014715**
- Date of Registration in DRKS: **2018/06/06**
- 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**



DRKS-ID: **DRKS00014715**

Date of Registration in DRKS: **2018/06/06**

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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **S-400/2016 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **J44 - Other chronic obstructive pulmonary disease**

Interventions/Observational Groups

- Arm 1: **370 patients enrolled into the COSYCONET cohort of COPD patients and having already participated successfully in the first trial with CT and MRI carried out within the COSYCONET subproject 7 between 2013 and 2016 (DRKS00005072, NCT02629432), are invited to attend the respective COSYCONET study center for a second assessment by MRI and CT.**

Characteristics

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

Primary Outcome

Identification of suitable image-based biomarkers to improve the prognosis of disease progression of COPD (Chronic Obstructive Pulmonary Disease) in comparison to clinical tests:

- **Use of the image-based assessment of the course of COPD: changes in lung perfusion MRI (e.g. PBV, PBF) and CT (e.g. PI10, LAA%, E/I-MLD) within a 3-year interval for the prediction of long-term disease progression as monitored by clinical tests (within the following 3 years; BODE index) . A progression of the disease is defined as an increase of the multidimensional 10-point BODE index by at least one point.**

Secondary Outcome

- **Predictive value of image-based quantitative biomarkers (changes in lung perfusion MRI (e.g. PBV, PBF) and CT (e.g. PI10, LAA%, E/I-MLD)) within the 3-year interval for rapid progression of COPD in comparison to clinical tests (BODE index, 3 and 6 year interval).**
- **Comparative analysis of image-based quantitative biomarkers (lung perfusion MRI, Air-trapping, airway- and emphysema metrics derived from CT) with established clinical biomarkers (BODE Index) for the quantitative evaluation of disease progression after 3 years (correlation of image - based biomarkers with clinical biomarkers over the same 3 year interval)**
- **Comparative analysis of image-based quantitative biomarkers (lung perfusion MRI, Air-trapping, airway- and emphysema parameters from CT) acquired during short-term interval (3-year interval) and established clinical biomarkers (BODE index) during long-term interval (6-year interval) for the quantitative evaluation of disease progression.**
- **Predictive value of image-based phenotypes (airway predominant or emphysema predominant phenotype) for the prognosis of COPD.**
- **Impact of tobacco consumption on structural and functional lung characteristics (quantitative lung perfusion MRI, air trapping, airway- and emphysema parameters from CT).**
- **Impact of frequent exacerbations on structural and functional lung characteristics in comparison to an exacerbation-free course of COPD.**
- **Establishment of an optimized MRI protocol for the monitoring of disease progression in COPD within a clinical context.**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- **University Medical Center Thoraxklinik, Heidelberg**
- **University Medical Center Klinik für Innere Medizin I, Pneumologie und Klinik für Diagnostische Radiologie, Kiel**
- **University Medical Center Medizinische Klinik II und Klinik für Diagnostische und Interventionelle Radiologie, Gießen**

- University Medical Center **Klinik und Poliklinik für Innere Medizin B, Pneumologie/Infektiologie und Institut für Diagnostische Radiologie u. Neuroradiologie, Greifswald**
- Medical Center **Pneumologisches Forschungsinstitut, LungenClinic Großhansdorf, Großhansdorf**
- other **Hamburger Institut für Therapieforchung, Hamburg**
- University Medical Center **Zentrum Innere Medizin, Abt. Pneumologie und Institut für Diagnostische und Interventionelle Radiologie, Hannover**
- University Medical Center **Klinik für Innere Medizin mit SP Pneumologie und Klinik für Diagnostische und Interventionelle Radiologie, Marburg**
- Medical Center **Medizinische Klinik 3/Schwerpunkt Pneumologie und Radiologie, Nürnberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/11/10**
- Target Sample Size: **370**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **40 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- **Patients enrolled into the COSYCONET main cohort of COPD (Chronic Obstructive Pulmonary Disease) patients, having already participated in the COSYCONET subtrial with CT and MRI performed between December 2013 and July 2016 (“MR-COPD I”, COSYCONET Subproject 7);**
- **MRI and CT images obtained in sufficient quality at baseline (“MR-COPD-I”)**

Exclusion criteria

- **Having undergone lung surgery (e.g. lung volume reduction, lung transplantation)**
- **Replaced pneumonia (antibiotic treatment necessary) in the last four weeks.**
- **Moderate or severe exacerbation requiring antibiotic treatment within the last 4 weeks prior to appointment**
- **Absence of informed consent**
- **Inability to understand the intention of the project**
- **Missing or incomplete MRI or CT examination in baseline (MR-COPD I).**
- **Insufficient quality of MRI and CT obtained at baseline (MR-COPD I)**

Contraindications to CT and MRI:

- **Due to the strong magnetic field**
- **patients with pacemaker**
- **patients with incompatible metallic implants**
- **Due to the use of Gadolinium based contrast agent**
- **allergy**
- **acute and chronic renal insufficiency (GFR <40 ml / min according to MDRD calculation)**
- **Pregnancy**
- **Claustrophobia**
- **Acute psychoses or other conditions that make the perception of the patient appear limited**

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Enrolling by invitation**
- 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.