

Trial Description

Title

Image-Based Structural and Functional Phenotyping of the COSYCONET Cohort Using MRI and CT (MR COPD).

Trial Acronym

MR COPD

URL of the trial

<http://www.asconet.net>

Brief Summary in Lay Language

This sub-trial is fully embedded into the competence network of Asthma and COPD (www.asconet.net) and complements the Cosyconet-Study with imaging methods. Up to 625 patients from the Cosyconet-Cohort will be asked to take part. Those patients will be scanned in different study centres once by Lowdose-CT and once by MRI with standardized protocols. The images will be pseudonymized and sent to the Imaging Bank at the University Hospital in Heidelberg where they will be analysed and stored.

The objective of this comparative trial is to prove that MRI - as the imaging modality without the use of ionizing radiation - can replace CT for structural and functional regional phenotyping of COPD and that in future it can be used in clinical routine.

Brief Summary in Scientific Language

This prospective trial aims to phenotype COPD by using Imaging methods. The identification of different COPD phenotypes, such as the “emphysema-type” and the “airway-type”, is important because therapy and prognosis will be different. Imaging might play a central role in diagnosing these phenotypes. So far computed tomography (CT) is regarded as the gold standard, but it involves ionizing radiation and lacks functional information. The medical problem addressed in this trial is the image-based phenotyping of COPD. The principal research question is whether magnetic resonance imaging (MRI) can replace CT for the characterization of COPD by “structural and functional phenotyping” on a regional basis. The sensitivity and specificity of MRI will be compared to Lowdose-CT serving as the gold standard. To achieve this goal, MRI and CT of the lung will be performed in a multi-centre cohort of 625 COPD-patients from the main COSYCONET cohort. Also, the reliability of the MRI results will be demonstrated. MRI phenotypes will be evaluated visually and using software with quantitative read-outs. The agreement of both will be determined. The additional information of MRI over CT will be assessed. A special focus will be to implement an image-based biomarker of pulmonary functional reserve derived from the MRI measurement of pulmonary perfusion, which will be correlated with results from pulmonary functions tests (e.g. the lung transfer factor for carbon monoxide

(TLCO)) the 6-minute walking test (6-MWD), and extrapulmonary disease manifestations.

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

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Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005072**
- Date of Registration in DRKS: **2013/07/19**
- Date of Registration in Partner Registry or other Primary Registry: **2015/12/14**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-656/2012 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Primary Registry-ID: **NCT02629432 (ClinicalTrials.gov)**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **625 COPD-patients already enclosed in the Cosyconet-Cohort will be scanned in different study centres once by Lowdose-CT and once by MRI with standardized protocols. The images will be pseudonymized and sent to the Imaging Bank at the University Hospital in Heidelberg where they will be analysed and stored.**
The objective of this comparative trial is to prove that MRI - as the imaging modality without the use of ionizing radiation - can replace CT for structural and functional regional phenotyping of COPD and that in future it can be used in clinical routine.

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

The primary goal of this prospective trial is to demonstrate the capability of MRI to replace CT for the characterization of COPD by “structural and functional phenotyping” on a regional basis. The sensitivity and specificity of MRI will be determined by comparison with CT, serving as the gold standard.

Secondary Outcome

Secondary endpoints are: Relative frequency of completed MRI examinations with diagnostic quality; agreement of visual and software-based phenotyping; comparative assessment of pulmonary functional reserve by perfusion MRI, pulmonary function tests (TLCO); and the six-minute walk test (6 MWT); and extrapulmonary disease manifestations.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Medizinische Klinik/Abt. Innere Medizin III/ Im Neuenheimer Feld 410, 69120 Heidelberg, Heidelberg**
- Medical Center **Thoraxklinik Heidelberg gGmbH/ Pneumologie und Beatmungsmedizin/ Amalienstraße 5/ 69126 Heidelberg, Heidelberg**
- University Medical Center **Klinik für Diagnostische und Interventionelle Radiologie, Baldingerstraße, 35043 Marburg, Marburg**

- University Medical Center **Institut für Klinische Radiologie, Ludwig-Maximilians-Universität München, Medizinische Poliklinik Innenstadt, Pettenkoferstraße 8a, 80336 München, München**
- Medical Center **Klinikum Nord-Nürnberg, Institut für Radiologie, Prof.Ernst-Nathanstr. 1, 90419 Nürnberg, Nürnberg**
- University Medical Center **Institut für Diagnostische Radiologie und Neuroradiologie, Universitätsmedizin Greifswald, Ferdinand Sauerbruch-Str., 17475 Greifswald, Greifswald**
- University Medical Center **Medizinische Hochschule Hannover, Abteilung für Diagnostische und Interventionelle Radiologie, Carl Neuberg Str. 1, 30625 Hannover, Hannover**
- University Medical Center **Klinik für Diagnostische und Interventionelle Radiologie, Universitätsklinikum des Saarlandes, 66421 Homburg/Saar, Homburg/Saar**
- University Medical Center **Universitätsklinikum Schleswig Holstein, Klinik für Diagnostische Radiologie, Campus Kiel, Arnold-Hellerstr. 3, Haus 23, 24105 Kiel, Kiel**
- University Medical Center **Universitätsklinikum Gießen und Marburg GmbH - Standort Gießen - Klinikstraße 33, 35392 Gießen, Giessen**
- other **Hamburger Institut für Therapieforchung (HIT) HmbH, Colonnaden 72, 20354 Hamburg, Hamburg**
- University Medical Center **Department für Bildgebung und Strahlenmedizin, Liebigstraße 20, 04103 Leipzig , Leipzig**
- University Medical Center **Institut für Diagnostische und Interventionelle Radiologie und Neuroradiologie, Hufelandstraße 55, 45147 Essen, Essen**
- Medical Center **Pneumologisches Forschungsinstitut, LungenClinic Großhansdorf, Wöhrendamm 80, 22927 Großhansdorf, Großhansdorf**
- University Medical Center **Klinische Forschung Pneumologie, Schwerpunkt Pneumologie, Gebäude 406, II. OG, III. Medizinische Klinik, Johannes Gutenberg-Universität Mainz K.d.ö.R., Langenbeckstrasse 1,55131 Mainz , Mainz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/12/19**
- Target Sample Size: **625**
- 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

The trial is fully embedded within the main cohort of the COSYCONET-study:

Key inclusion criteria

- **Male or female**
- **Age >40 years**
- **Diagnosis of COPD (GOLD criteria)**
- **Available for repeated study visits**

Exclusion criteria

**Having undergone lung surgery (e.g., lung volume reduction, lung transplant);
Moderate or severe exacerbation within the last 4 weeks prior to visit 1; Unable
to understand the intention of the project; lack of signed informed consent**

Addresses

■ **Primary Sponsor**

**Universitätsklinikum Heidelberg
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■ **Contact for Scientific Queries**

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URL: **[---]***

■ **Contact for Public Queries**

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Radiologie, Sektion Pulmonale Radiologie
Ms. Kerstin Burmester**

Contact for Public Queries

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■ **Collaborator, Other Address**

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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.)**

**BMBF
Bundesministerium für Bildung und Forschung**

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53175 Bonn
Germany**

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Fax: [---]*

E-mail: [---]*

URL: <http://www.bmbf.de>

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/07/07**

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.