Trial Description

Title

Pulmonary Hypertension Registry Mainz

Trial Acronym

PHYREM

URL of the trial

[---]*

Brief Summary in Lay Language

Patients with pulmonary hypertension will be cared for clinical means over a period of 3 years and the examination results will be added to a registry. The goal of the study is to discover a possibly occuring impairment or worsening of the function of the heart and lungs as early as possible by follow-up visits for treatment purposes. In addition, indicators (so-called biomarkers) will be indentified in blood samples which provide information about the current condition of the lungs and heart as well as the exspected clinical course.

Brief Summary in Scientific Language

The goal of the prospective epidemiological observational study is to evaluate the diagnostic, prognostic, and therapeutic strategies as well as the clinical long-term course of patients with confirmed diagnosis of pulmonary hypertension (PH).

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006245**
- Date of Registration in DRKS: **2015/04/30**
- 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.: **837.406.14 (9645) , Ethik-Kommission bei der**

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Ethics Approval/Approval of the Ethics Committee: **Approved**
Landesärztekammer Rheinland-Pfalz

Secondary IDs

Health condition or Problem studied

- ICD10: **I27.2 - Other secondary pulmonary hypertension**
- ICD10: **I27.0 - Primary pulmonary hypertension**

Interventions/Observational Groups

- Arm 1: **Patients with confirmed diagnosis of pulmonary hypertension will be followed every 6 months over a period of 3 years by documentation of clinical, imaging, and laboratory examination results.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- 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

This prospective non-interventional study aims to evaluate the diagnostic, prognostic, and therapeutic strategies as well as the clinical long-term course of patients with confirmed diagnosis of pulmonary hypertension.

Secondary Outcome

(1) To determine the prognostic value of the following parameters at diagnosis in relation to the patients' clinical long-term outcome: (a) clinical (symptoms, clinical signs, predisposing (history) criteria and comorbidities), (b) imaging (echocardiography, if indicated: V/Q lung scan, computed tomographic (CT) angiography, magnetic resonance tomographic (MRT) angiography, conventional selective pulmonary angiography), and (c) laboratory (biomarker tests); (2) to find out optimal „cut-off"-values of different biomarkers from the categories mentioned above and to develop novel algorithms for risk stratification; (3) to analyze the course of these parameters or biomarkers as indicators of the response to therapy; (4) to identify novel diagnostic and prognostic biomarkers (under development and resulting from translational CTH research) in different patient groups of PH; (5) to investigate the influence of established and new therapeutic substances/schemes, and/or surgical/interventional therapies, on the prognosis, the functional status, and life quality of patients and to gather the progresses related to PH management on the long-term outcome.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Centrum für Thrombose und Hämostase (CTH) und 2. Medizinische Klinik, Mainz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/12/14**
- 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

(1) Confirmed diagnosis of pulmonary Hypertension and (2) written informed consent of study participants or their legal representative.

Exclusion criteria

Anticipated non-compliance or inability to adhere to study protocol (deficient willingness or ability to cooperate).

Addresses

- **Primary Sponsor**

  Universitätsmedizin der Johannes Gutenberg-Universität Mainz
  Langenbeckstraße 1
  55131 Mainz
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.cth-mainz.de**

- **Contact for Scientific Queries**

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  55131 Mainz
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  Telephone: **06131/17-8297**
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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.)**

  Bundesministerium für Bildung und Forschung Dienstsitz Berlin
  Friedrichstraße 130 B
  10117 Berlin
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.bmbf.de**
- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

  Actelion Pharmaceuticals Deutschland GmbH
  Konrad-Goldmann-Str. 5b
  79100 Freiburg i.B.
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **121**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **121**

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.*