Trial Description

Title

**Follow-Up after Acute Pulmonary Embolism -
a Prospective Observational Multicenter Cohort Study**

Trial Acronym

FOCUS

URL of the trial

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Brief Summary in Lay Language

In this observational study emphasis is put on the registration of persistent sequelae after an acute episode of pulmonary embolism. Especially markers indicative of the development of chronic postembolic pulmonary hypertension will be looked for.

Brief Summary in Scientific Language

Objectives: To determine, over a 2-year follow-up period, the incidence of chronic thromboembolic pulmonary hypertension (CTEPH) or post-PE impairment after an index episode of acute pulmonary embolism (PE).
Population: A total of 1000 patients with acute symptomatic PE will be included in the study:
Inclusion Criteria
1) Objectively confirmed diagnosis of acute symptomatic PE by multidetector computed tomography (CT), pulmonary angiography, or V/Q lung scan according to established diagnostic criteria, with or without symptomatic deep vein thrombosis;
2) Ability of subject to understand character and individual consequences of participation in the study;
3) Written informed consent available before enrollment in the study;
4) Age ≥18 years.
Exclusion Criteria
1) Subjects unwilling or unable to sign the informed consent form;
2) Patients in whom the diagnosis of PE is an incidental finding during diagnostic workup for another disease;
3) Patients with previously diagnosed chronic thromboembolic pulmonary hypertension;
4) No subject will be enrolled in this study more than once.
Primary Outcomes:
1) Confirmed diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) at any time during 2 year-follow-up;
2) Post-PE impairment at >1 follow-up visit, defined by deterioration (compared to the previous visit or to the findings at discharge) by at least one category, or persistence of the greatest-severity category, in >1 of the “a” (echocardiographic) parameters plus deterioration by at least one category (or

persistence of the greatest-severity category) in >1 of the “b” (clinical, functional, or laboratory) parameters

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: **DRKS00005939**
- Date of Registration in DRKS: **2014/07/03**
- 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.: **837.440.13 (9125) , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

Health condition or Problem studied

- ICD10: **I26.9 - Pulmonary embolism without mention of acute cor pulmonale**
- ICD10: **I27 - Other pulmonary heart diseases**

Interventions/Observational Groups

- Arm 1: **Patients with confirmed acute pulmonary embolism will be treated according to current guidleines and invited to control vists in the clinic after 3, 12 and 24 months where data, including the results of a 6-minutes walking test and cardiopulmonary exercise testing will be recorded and 2 QoL questionnaires will be administered to the patients**

Characteristics

- Study Type: **Non-interventional**

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- 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

1) Confirmed diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) at any follow-up visit (at 3, 12 und 24 months) during 2 year-follow-up;
2) Post-PE impairment at ≥1 follow-up visit, defined by deterioration - compared to the previous visit or to the findings at discharge - by at least one category, or persistence of the greatest-severity category, in ≥1 of the echocardiographic parameters PLUS deterioration by at least one category or persistence of the greatest-severity category in ≥1 of the clinical, functional, or laboratory parameters

Secondary Outcome

Overall mortality, recurrent deep vene thrombosis od pulmonal embolism, stroke, functional impairment defined by oxygen comsumption during exercise test, 6-minute walkingtest and Borg's dyspnoea Index, echcardiographic evidence of pulmonal hypertension, changes in quality of life at 3, 12 and 24 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Centrum für Thrombose und Hämostase, Mainz**
- University Medical Center **Dresden**
- University Medical Center **Leipzig**
- Medical Center **DRK Kliniken Berlin Westend, Berlin**

- University Medical Center **Greifswald**
- University Medical Center **Gießen**
- University Medical Center **Köln**
- University Medical Center **Universitätsklinikum des Saarlandes, Homburg**
- University Medical Center **Heidelberg**
- Medical Center **Krankenhaus Neuwittelsbach, München**
- University Medical Center **München**
- Medical Center **Städt. Klinikum Bogenhausen, München**
- Medical Center **Klinikum Würzburg Mitte, Würzburg**
- University Medical Center **Göttingen**
- University Medical Center **Hannover**
- Medical Center **Unfallkrankenhaus Berlin, Berlin**
- Medical Center **Klinikum Esslingen, Esslingen am Neckar**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/09/29**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1) Objectively confirmed diagnosis of acute symptomatic PE by multidetector computed tomography (CT), pulmonary angiography, or V/Q lung scan according to established diagnostic criteria (1), with or without symptomatic deep vein thrombosis;
2) Ability of subject to understand character and individual consequences of participation in the study;
3) Written informed consent must be available before enrollment in the study;
4) Age ≥18 years

Exclusion criteria

1) Subjects unwilling or unable to sign the informed consent form;
2) Patients in whom the diagnosis of PE is an asymptomatic incidental finding during diagnostic workup for another disease;
3) Patients with previously diagnosed chronic thromboembolic pulmonary hypertension;
4) No subject will be allowed to enroll in this study more than once.

Addresses

■ **Primary Sponsor**

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

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

■ **Contact for Scientific Queries**

Centrum für Thrombose und Hämostase,Universitätsmedizin der Johannes Gutenberg-Universität Mainz
Mr. Univ. Prof., Dr. med. Stavros Konstantinides
Langenbeckstraße 1
55131 Mainz
Germany

Telephone: **06131 17 8297**
Fax: **[---]***
E-mail: **stavros.konstantinides at unimedizin-mainz.de**
URL: **www.klinik.uni-mainz.de**

■ **Contact for Public Queries**

Centrum für Thrombose und HämostaseUniversitätsmedizin der Johannes Gutenberg-Universität Mainz
Mr. Prof. Stavros Konstantinides
Langenbeckstraße 1
55131 Mainz
Germany

Telephone: **06131 17 8382**
Fax: **[---]***
E-mail: **sabrina.rump at unimedizin-mainz.de**
URL: **[---]***

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.)**

  Bayer Vital GmbH
  51368 Leverkusen
  Germany

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2020/09/08**

Trial Publications, Results and other documents

- Paper **Stavros V. Konstantinides et al: Late outcomes after acute pulmonary embolism: rationale and design of FOCUS, a prospective observational multicenter cohort study. J Thromb Trhombolysis 2016.**

** 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.*