Trial Description

Title

HiGHmed - Use Case Cardiology (HiGHmed-UCC) - Establishment of a registry of patients with chronic heart failure as a part of the "HiGHmed-consortium"

Trial Acronym

HiGHmed-UCC

URL of the trial

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Brief Summary in Lay Language

HiGHmed is one of four consortia funded by the Federal Ministry of Education and Research (BMBF) under the “Medical Informatics” funding scheme as part of the Medical Informatics Initiative. Together with partners from industry and research, standardized methods in the form of information technology solutions for the exchange of clinical data across clinical borders are to be developed and established. In the context of the Use Case Cardiology, structured patient data of the standard treatment of a patient with chronic heart failure (including treatment data already collected) are to be documented. In addition, half-yearly telephone enquiries are carried out to query hospital stays of patients with chronic heart failure. This is initially planned for a period of 3 years.

Brief Summary in Scientific Language

The aim of the project is to establish an IT environment (MeDIC-Medical Data Integration Center) for standardised diagnostic assessment. Retrospective and prospective treatment data of patients with chronic heart failure will be systematically recorded. The aim is to identify patients who are at high risk of hospitalization due to the worsening of the chronic heart failure and/or have a poor prognosis (mortality).

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: **DRKS00015802**
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Date of Registration in DRKS: **2018/11/14**

- 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.: **8089_BO_K_2018 , Ethikkommission der Medizinischen Hochschule Hannover**

Secondary IDs

Health condition or Problem studied

- ICD10: **I50.9 - Heart failure, unspecified**

Interventions/Observational Groups

- Arm 1: **Patients with chronic heart failure**

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Characteristics

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

Primary Outcome

Hospitalization due to worsening of heart failure and/or all-cause mortality.

Secondary Outcome

(1) Determination of a standard data set for patients with chronic heart failure
(2) Provision of a structured recording method for the assessment of findings
(3) Structuring and collection of retrospective and prospective care data of patients with chronic heart failure in a medical data integration Center
(4) Provision of collected care data for long-term research/development of new research questions

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Medizinische Hochschule, Hannover**
- University Medical Center **Universitätsklinikum Heidelberg, Heidelberg**
- University Medical Center **Universitätsmedizin Göttingen, Göttingen**
- University Medical Center **Universitätsklinikum Würzburg, Würzburg**
- University Medical Center **Universitätsklinikum Schleswig-Holstein, Kiel**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/11/23**
- Target Sample Size: **6250**
- 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) Age ≥ 18 years

(2) Chronic Heart Failure
(3) ability to give consent
(4) conducted patient information and presence of patient´s written declaration of consent

Exclusion criteria

(1) Life expectancy less than 6 months due to non-cardiological pre-existing conditions
(2) Inability to give consent

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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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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Germany

Telephone: **030 / 18 57-0**
Fax: **030 / 18 57-83601**
E-mail: **bmbf at bmbf.bund.de**
URL: **www.bmbf.de/**

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.*