DRKS-ID: **DRKS00012555**
Date of Registration in DRKS: **2018/01/04**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

Deutsches Register Klinischer Studien
German Clinical Trials Register

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

Trial Description

Title

Multidimensional analysis of causes for the low prevalence of ambulatory peritoneal dialysis in Germany (MAU-PD)

Trial Acronym

MAU-PD

URL of the trial

http://www.mau-pd.de

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

From a medical perspective, peritoneal dialysis (PD) and hemodialysis (HD) are equivalent treatment options for patients with chronic kidney disease (CKD). Findings show that PD rates vary considerably worldwide (e.g., Hong Kong 79.4%, Sweden 23.8%, Germany 5.4%, and Luxembourg 0.7%). The objective of the project is to identify causal factors for the low PD rate in Germany. The effect of these factors can be the promotion or inhibition of PD from different perspectives of patients, physicians, nurses, and sickness funds. In this cross sectional study, our focus is on the health care situation of dialysis patients at a local level as well as the different costs and cost categories (HD vs. PD). Furthermore, we analyze the identification and weights of factors of patients, physicians, and nurses that are relevant for modality choice. The study is funded by the Innovation Committee of the Federal Joint Committee.

The health care situation is represented by secondary data analysis. Data resources consist of panel medical care accounting data produced by the Central Research Institute of Ambulatory Health Care of the National Association of Statutory Health Insurance Physicians; claims data from two cooperating statutory health insurance companies; and quality assurance data from KfH (QiN – Quality in Nephrology), an ambulatory dialysis provider in Germany. Using a mixed methods design, we conduct qualitative individual interviews with patients and focus groups with nephrologists and nurses as well as a quantitative survey using a standardized questionnaire. Different questionnaires are targeted at health care professionals (physicians, dialysis nursing managers, and dialysis nursing staff) and patients. This data enables the identification of causal factors for the uptake of PD as well as its distribution and relevance.

We expect a representative quantitative analysis of factors influencing the treatment choice for or against PD. Finally, an action plan including practical

solutions is derived from the results of this analysis. These results can reveal approaches at different levels of health care delivery, including at the organizational level with internal and external organizational structures and processes and at the individual level of physicians and patients. In addition, the results open up a major discussion for all players in the health care sector (e.g., dialysis providers, funders, etc.).

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00012555**
- Date of Registration in DRKS: **2018/01/04**
- 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.: **17-299 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1207-0719**
- Other Secondary-ID: **VfD_MAU-PD_17_003843 (Versorgungsforschung Deutschland Datenbank)**

Health condition or Problem studied

- ICD10: **N18.5 - Chronic kidney disease, stage 5**

Interventions/Observational Groups

- Arm 1: **qualitative research part:**
  interviews (n=12), patients with dialysis treatment (PD+HD); focus groups with resident nephrologists (n=16); focus group PD-specialized care givers (n=8); focus group care managers in dialysis practice
- Arm 2: **quantitative research part:**
  survey patients with dialysis treatment (n≈2.000); survey resident nephrologists (n≈1.200); survey care managers in dialysis practice (n≈500); survey PD-specialized care givers (n≈700)

- Arm 3: **structural/economical secondary data analysis: account data from Statutory Health Insurance Physicians; medical documentary data from KfH nephro centres (QiN); dialysis data from health insurances**

Characteristics

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

Primary Outcome

analysis of relevant needs (structural environment; personal attitudes) after evaluation of qualitative studies (11/2017 - 07/2018)

Secondary Outcome

PD-rate in Germany: analysis of the significant structural and influencing factors for patients, physicians and care givers regarding dialysis options (HD vs. PD); surveys + secondary data analysis; 08/2018 - 12/2019

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Kongresse etc. (Interviewpartner/Fokusgruppen)**
- other **Krankenkassen (Dialysepatienten), [---]***
- Doctor's Practice **öffentliche Register (Nephrologen+Pflegepersonal)**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/11/01**
- Target Sample Size: **4700**
- 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

dialysis patients (hemo- and peritoneal dialysis) - resident nephrologists - caregivers in dialysis centres

Exclusion criteria

under age of 18

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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Fax: **[---]***
E-mail: **info at if.g-ba.de**
URL: **https://innovationsfonds.g-ba.de/**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2020/04/30**

Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) **Study Protocol MAU-PD**
- Trial results **Personal attitudes and PD**

** 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.*