PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Initiative for Patient Outcomes in Dialysis - PD (IPOD-PD Study)

Trial Acronym

IPOD-PD

URL of the trial

[---]*

Brief Summary in Lay Language

**The aim of the study is to asses the hydration status of incident peritoneal dialysis (PD)
patients and its evolution over a period of four years, independent of the PD treatment
modality (APD or CAPD) and the PD solution type.**

Brief Summary in Scientific Language

**Achieving optimal fluid balance remains a major clinical challenge in peritoneal dialysis
(PD) patients. With the recent development of a new bioimpedance spectroscopy (BIS) device,
the BCM-Body Composition Monitor (BCM), it is now possible to quantify deviations of
hydration status and to define target weight directly.

It has been observed that more than 50% of the PD patients are overhydrated, as compared to
the healthy population. This overhydration seems to be associated with modifiable
practice-related factors, such as correct PD prescription according to membrane transport
status, and dietary fluid intake.

The aim of this study is to assess the hydration status of incident PD patients, and
diagnose the underlying reasons for incorrect fluid status. In addition, changes in fluid
status, residual renal function and nutritional status, over a follow-up period of up to
four years will be registered.**

The investigators assume that the use of the BCM-Body Composition Monitor (BCM) provides quantitative measurement of hydration status and thereby supports physicians in identifying patients who are not euvolaemic. Hence, the BCM allows an improved management of underlying causes of non-euvolaemic hydration state and appropriate monitoring of fluid status.

Organizational Data

- DRKS-ID: **DRKS00006506**
- Date of Registration in DRKS: **2015/01/15**
- Date of Registration in Partner Registry or other Primary Registry: **2011/01/26**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01285726 (ClinicalTrials.gov)**
- Sponsor-ID: **BCM-PD-02-INT (Fresenius Medical Care Deutschland GmbH)**

Health condition or Problem studied

- Free text: **Chronic Renal Failure**
- ICD10: **N18 - Chronic kidney disease**

Interventions/Observational Groups

- Arm 1: **Other: Non-interventional study**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***
- Blinding: **[---]***
- Who is blinded: **[---]***

Study Type: **Non-interventional**

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

Allocation: **[---]***

Blinding: **[---]***

Who is blinded: **[---]***

- Control: **[---]***
- Purpose: **[---]***
- Assignment: **[---]***
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Hydration status; time frame: Every three months over a period of four years; Assessed via body composition measurements (Overhydration, total body water (TBW), extracellular water (ECW), intracellular water (ICW)) (Overhydration, total body water (TBW), extracellular water (ECW), intracellular water (ICW))

Secondary Outcome

- Residual renal function; time frame: Every three months over a period of four years
- Peritoneal transport status; time frame: Every three months over a period of four years
- Time to change to haemodialysis; time frame: Four years
- Changes in PD prescription; time frame: Four years

Countries of recruitment

- AT **Austria**
- BE **Belgium**
- BA **Bosnia and Herzegovina**
- BR **Brazil**
- HR **Croatia**
- CU **Cuba**
- CZ **Czech Republic**
- DK **Denmark**
- EE **Estonia**

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- FI **Finland**
- FR **France**
- DE **Germany**
- GR **Greece**
- IN **India**
- IL **Israel**
- IT **Italy**
- KR **Korea, Republic of**
- LV **Latvia**
- LT **Lithuania**
- NL **Netherlands**
- NO **Norway**
- PT **Portugal**
- ES **Spain**
- SE **Sweden**
- CH **Switzerland**
- TR **Turkey**
- UK **United Kingdom**
- VE **Venezuela, Bolivarian Republic of**

Locations of Recruitment

- **KfH Nierenzentrum Bottrop, Bottrop**
- **Klinikum Braunschweig, Braunschweig**
- **Nierenzentrum Heidelberg, Heidelberg**
- **Nieren und Hochdruckzentrum Kiel, Kiel**
- **Robert Bosch Krankenhaus, Stuttgart**
- **Nephrologisches Zentrum Velbert Innere Medizin und Nephrologie, Velbert**
- **Nephrologische Praxis Wiesbaden, Wiesbaden**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2011/01/31**

Planned/Actual: **[---]***

(Anticipated or Actual) Date of First Enrollment: **2011/01/31**

- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

- Incident patients directly before start of peritoneal dialysis

- Patients in whom routine measurement of body composition monitoring is performed

Exclusion criteria

- Patients treated with HD before start of PD

- Patients in whom body composition monitoring cannot be performed

Addresses

- **Primary Sponsor**

  Fresenius Medical Care Deutschland GmbH

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

- **Contact for Scientific Queries**

  Ospedale San Bartolo
  Claudio Ronco, Prof

Contact for Scientific Queries

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- **Contact for Public Queries**

Ospedale San Bartolo
Claudio Ronco, Prof

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

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

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

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: 1

- Last processed date by ClinicalTrials.gov: 2014/07/16

** 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.*