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

Trial Description

Title

The Eurocyst Initiative: Building a Reference Center Network Across EUROpe to Establish a Large-scale Longitudinal Observational Cohort of Autosomal Dominant polyCYSTic Kidney Disease (ADPKD) Patients

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

EuroCYST initiative aims to build a large, well-characterized cohort of Autosomal Dominant polyCYSTic Kidney Disease (ADPKD) subjects who are followed in a longitudinal observational cohort study has the potential to identify progression factors and biomarkers, and to assess disease stage specific mortality, morbidity and health care costs.

Brief Summary in Scientific Language

The EuroCYST Initiative aims to build a network of ADPKD reference centers across Europe and to establish a large-scale observational cohort of ADPKD patients for the purpose of studying the pathogenesis, rate of disease progression, progression rate modifiers, disease stage specific morbidity, mortality, health economic issues and the predictive value of biomarkers in ADPKD. Overall 1,100 patients will be enrolled in 14 study sites across Europe and will be followed up for at least three years. The ADPKD reference center network across Europe and the observational cohort study will enable European ADPKD researchers to gain insight into the natural history, heterogeneity and associated complications of the disease as well as how it affects the lives of patients across Europe.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006478**
- Date of Registration in DRKS: **2014/11/05**
- Date of Registration in Partner Registry or other Primary Registry: **2014/02/24**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02187432 (ClinicalTrials.gov)**
- Sponsor-ID: **Eurocyst (University of Zurich)**

Health condition or Problem studied

- Free text: **Autosomal Dominant Polycystic Kidney Disease**
- ICD10: **Q61.2 - Polycystic kidney, autosomal dominant**

Interventions/Observational Groups

Characteristics

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

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

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

Control: **[---]***

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

Primary Outcome

- disease progression; time frame: participants will be followed annually for at least 3 years; Investigate disease progression and association of disease biomarkers with the onset and severity of ADPKD-related outcomes.

Secondary Outcome

- QOL (Quality of Life); time frame: participants will be followed annually for at least 3 years; Evaluate and establish the level of disease impact on self-estimated health status, pain, QoL, socioeconomic status (SES), ADPKD-related health burden, health care resource use.

Countries of recruitment

- BE **Belgium**
- CZ **Czech Republic**
- FR **France**
- DE **Germany**
- IT **Italy**
- NL **Netherlands**
- ES **Spain**
- CH **Switzerland**
- TR **Turkey**
- UK **United Kingdom**

Locations of Recruitment

- **Charité Universitätsmedizin Berlin, Berlin**
- **University Hospital Erlangen, Erlangen**
- **University Hospital Freiburg, Freiburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2013/08/31**
- Target Sample Size: **1100**
- 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

- Participants ≥ 18 years;

- Clinical diagnosis of ADPKD based on kidney imaging and family history;

- Estimated Glomerular Filtration Rate (eGFR) ≥ 30 ml/min/1.73m2 (Chronic Kidney Disease Epidemiology Collaboration(CKD-EPI)- formula);

- Provided written informed consent.

Exclusion criteria

- Receiving chronic renal replacement therapy before enrollment (dialysis, allograft) or anticipated in the following 12 months after enrollment;

- Participation in a clinical trial aiming to modify disease outcome one year or less before enrollment in the EuroCYST study;

- New York Heart Association (NYHA) stadium IV.

Addresses

- **Primary Sponsor**

  University of Zurich

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
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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 ongoing**
- Study Closing (LPLV): **[---]***

Deutsches Register Klinischer Studien
German Clinical Trials Register

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: 2

- Last processed date by ClinicalTrials.gov: 2014/12/02

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.