The DIPAK Observational Cohort Study: a multi-center, longitudinal, observational study to investigate renal disease progression and association of disease biomarkers with renal disease progression and ADPKD-related outcomes.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON47875

Source
ToetsingOnline

Brief title
The DIPAK Observational Cohort Study

Condition

- Renal and urinary tract disorders congenital
- Nephropathies

Synonym

Autosomal Dominant Polycystic Kidney Disease, or polycystic kidney disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: de Nierstichting

Intervention

Keyword: ADPKD, observational, prevention, renal disease progression

Outcome measures

Primary outcome

To investigate disease progression factors and association of disease

biomarkers with the onset and severity of ADPKD-related outcomes like

hypertension, renal function, renal pain renal, albuminuria, renal urine

concentrating ability, hematuria, cyst infection, nephrolithiasis and others.

Secondary outcome

To summarize the levels of self-estimated health status, pain, QoL,

ADPKD-related health burden, health care resource use.

Study description

Background summary

Autosomal dominant polycystic kidney disease (ADPKD) is characterized by progressive cyst formation in both kidneys, leading to end stage renal disease. It is the most common hereditary disease, with a prevalence rate of 1 in 400 to 1 in 1,000 persons. ADPKD is an important cause of renal failure. Unfortunately, there are not many marketed proven effective therapies to halt disease progression yet. At the moment, one drug has been proven to be effective and a number of other drugs are being evaluated. Now efficacy of one drug has been established, and in the future probably others, pivotal questions are whom to treat and when to initiate such treatment. Given that ADPKD is a

progressive condition, it seems most appropriate to initiate intervention as early in life as possible to delay or prevent long-term consequences, including renal failure and cardiovascular and liver complications. On the other hand, ESRD occurs in only approximately 70% of affected subjects and not all affected subjects will experience disease related adverse health outcomes. It will therefore not be appropriate to expose all subjects to life long medical treatment that may cause adverse events.Therefore, the present studie is designed large scale observational cohort with sufficient duration of follow-up to investigate new biomarkers and determinants to predict and monitor renal function decline.

Study objective

Overall aim: Given the aforementioned rationale it is therefore important to know the natural course of the disease and stage specific morbidity and mortality factors in a longitudinal observational study, to evaluate the levels of and associations between the impacts of patients reported disease outcome (quality of life (QoL), pain, self-estimated health status, health burden) and to develop markers that alone, or in combination, predict prognosis in ADPKD.

Primary Objective: To investigate renal disease progression and association of disease biomarkers with renal disease progression, and with the onset and severity of ADPKD-related outcomes.

Secondary objectives: 1. To investigate liver disease progression and association of disease biomarkers with liver disease progression, and with the onset and severity of ADPKD-related outcomes. 2. To evaluate and establish the level of the renal and liver disease impact on patient reported outcomes. 3. To explore and identify additional parameters of disease progression.

Study design

Multicenter, longitudinal, observational investigator driven cohort study to investigate renal disease progression and association of disease biomarkers with renal disease progression in subjects with based on the Ravine criteria (with number of cysts known from a previous ultrasound or magnetic resonance imaging [MRI]) over a period of at least 6 years.

Study burden and risks

When compared to routine clinical care the burden and risk associated with participation are:
• In general ADPKD patients, depending on their renal function will visit an out-patient department once every 3 to 12 months routinely. Therefore this study imposes 0 extra visits to an outpatient department when compared to routine care, since the observationele visits are every 12 months.

• In general ADPKD patients when visiting an out-patient department collect 24hr urine and blood is drawn for routine clinical chemistry. During the every visit extra blood will be drawn for biobanking.
• 4 times a MRI of liver and kidneys (without contrast)
• 4 times a questionnaire

The subjects have no potential benefit.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Diagnosis of ADPKD, based upon the modified Ravine criteria or documented by treating
nephrologist or internist.

2. Age 18 years and older.
3. Providing informed consent.

Exclusion criteria

• Patients, who are unlikely to adequately comply with the trial*s procedures (due for instance to medical condition likely to require an extended interruption or discontinuation)
• Patients taking medications or having concomitant illnesses that are likely to influence the natural course of ADPKD (e.g. nephrotoxic medications such as chronic NSAID, cyclosporine, lithium and immunosuppressant use, and e.g. diabetes mellitus and patients with proteinuria > 1 g/24hr).
• Patients, who receive renal function replacement therapy
• Pregnancy at moment of inclusion
• Patients with a life expectancy less than 1 year at moment of inclusion

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2013
Enrollment:	750
Type:	Actual

Ethics review

Approved WMO

Date:	24-05-2013
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-09-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-01-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-12-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-08-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-08-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43496.042.13