DMP title

Project Name My plan (FWO DMP) - DMP title

Project Identifier 11M8422N

Principal Investigator / Researcher Pieter Schellekens

Project Data Contact Pieter.schellekens@kuleuven.be

Description Autosomal Dominant Polycystic Kidney Disease (ADPKD) is the most common monogenetic inherited kidney disease. Recently we have reviewed the literature on an intriguing finding, notably ADPKDâ€™s association with lower blood cell counts. The strongest association in literature so far has been observed with alterations in the lymphocytic lineages, but also other white blood cell subtypes and thrombocytes are affected. The clinical significance of the diseaseâ€™s association with lower blood cell counts is largely unknown. Previous data already showed that the affected genes in ADPKD are also expressed in lymphocytes and interfere with lymphocyte proliferation and functioning. This research project seeks (1) to further explore the clinical association between cytopenia and ADPKD in well-defined clinical cohorts and to study its link with clinical outcomes, (2) to study the expression and functional impact of molecular PKD-defects in peripheral blood derived lymphocytes and neutrophils from ADPKD and non-ADPKD control patients and (3) to study Ca2+ signaling, considered to be central in ADPKD pathogenesis, in myeloid and lymphoid cell lines with and without functional polycystin-1 and-2. The results of this combined clinical and fundamental research project are expected to shed a new light on the functional role of polycystins in blood cells and the important inflammatory component in the pathogenesis of ADPKD.

Institution KU Leuven

1. General Information

Name applicant

Pieter Schellekens

FWO Project Number & Title

11M8422

Cytopenia in ADPKD: from clinical association to mechanism of disease?

Affiliation

- KU Leuven

2. Data description

Will you generate/collect new data and/or make use of existing data?

- Generate new data
- Reuse existing data

Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

Type of data	Format	Volume	How created
WORK PACKAGE 1			
Clinical an biochemical information of the transplant cohort of patients	.xls	5-10 MB	Standardized extraction from the individual patient files in KWS
Clinical an biochemical information of the pediatric cohort of patients	.xls	5-10 MB	Standardized extraction from the individual patient files in KWS
Clinical an biochemical information of the CKD cohort of patients	.xls	5-10 MB	Standardized extraction from the individual patient files in KWS
WORK PACKAGE 2			
Western blots	.jpeg	1-10GB	Directly derived from imager
RT-PCR	.jpeg	1-10GB	Directly derived from imager
MSD analysis	.xls	100-1000kB	Copied from the imager
ELISA’s	.xls	100-1000kB	Copied from the imager
WORK PACKAGE 3			
RT-PCR	.jpeg	1-10GB	Directly derived from the imager
Western blots	.jpeg	1-10GB	Directly derived from the imager
MSD analysis	.xls	100-1000kB	Directly derived from the imager
ELISA’s	.xls	100-1000kB	Directly derived from the imager

3. Legal and ethical issues

Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- Yes

Privacy Registry Reference: Ethische Commissie Onderzoek UZ/ KU Leuven s65616, s59500 and s64953.

Short description of the kind of personal data that will be used:

Work package 1: Pediatric cohort (s59500) + Transplant cohort (s64953) + CKD cohort (not yet in place):

- Age, gender
- Antropometric: lenght, weighth, BMI
- Clinical: age at diagonis, reason of diagnosis, previous infections/malignancies or transplant

rejections, age at transplantation, age at start dialysis ...

- Genetic: mutation in PKD1/PKD2/GANAB (cDNA change, amino-acid change, type of mutation, exon/intron number)
- Biochemical: blood cell counts, inflammation, electrolytes, urinalysis, vitamins, immunoglobulines, complent factors,...
- Comorbidities
- Radiologic: total kidney volume on ultrasound, CT or MRI

Work package 2 (s65616)

- Age, gender
- Antropometric: lenght, weighth, BMI
- Smoking habit
- Clinical: age at diagonis, reason of diagnosis, date last infection, date last vaccination
- Genetic: mutation in PKD1/PKD2/GANAB (cDNA change, amino-acid change, type of mutation, exon/intron number)
- Biochemical: blood cell counts, inflammation markers (sedimentation & CRP), kidney function (creatinine and eGFR).

Work package 3: No personal data involved.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, add the reference to the formal approval by the relevant ethical review committee(s)

- Yes

Work package 1:
Pediatric cohort: s59500
Transplant cohort: s64953
CKD cohort: not yet in place
Work package 2: s65616
Work package 3: n/a

Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- No

Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?

- No

4. Documentation and metadata

What documentation will be provided to enable reuse of the data collected/generated in this project?

1. Concerning Western blots following information will be noted: date of the experiment, loading conditions, protein concentrations, primary and secondary Ab used, settings on the imager (ECL or ECL plus imaging). The methodology and protocol will be described in detail in the lab book.
2. Concerning ELISAs following information will be noted: date of the experiment, plate setup, imager used. The methodology and protocol will be described in detail in the lab book.
3. Stimulation data from the stimulation assay (work package 3) will be collected per test, including a txt file with a clear description of what the data represent and how they were generated. The name of the folder will contain the composition, temperature and a reference to the loading conditions of the considered material (a .txt file explaining the naming will be maintained).

Will a metadata standard be used? If so, describe in detail which standard will be

used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- No

5. Data storage and backup during the FWO project

Where will the data be stored?

1. The different data files will be kept on our research unit central storage facility. Copies can be made and kept on personal devices.

2. Since we will be working with sensitive pseudoanonymised (coded) personal data, data will be stored in the university's secure environment for private data.

How is backup of the data provided?

The data will be stored on the university's central servers with automatic daily back-up procedures.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available then explain how this will be taken care of.

- Yes

Sufficient storage en backup capacity is avalaible provided by both the UZ Leuven and KU Leuven. We will only work with small data sets. The storage and backup capacity will not be an issue for this project.

What are the expected costs for data storage and back up during the project? How will these costs be covered?

No additional costs.

Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Data will be saved in a password protected and shared folder from the UZ Leuven/ KU Leuven.

6. Data preservation after the FWO project

Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).

All collected data will be retained 15 years after the collection (cfr. s65616, s59500).

Where will the data be archived (= stored for the longer term)?

The data will be stored on the university's central servers (with automatic back-up procedures) for at least 15 years, conform the KU Leuven RDM policy.

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?

The project will only creates small datasets (maximum 10GB), no additional cost for data storage and preservation.

7. Data sharing and reuse

Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

- Yes. Specify:

1. Included patients gave consent for the preservation of biological samples and clinical data for 15 years for future research.

2. Data will not be shared, except within the project team collaborators, unless stated otherwise in the study protocol and the applicable informed consent signed by the patients.

Which data will be made available after the end of the project?

Anonymised transcripts of the stimulation assays, western blots and ELISAs will be made

available through peer-reviewed publications.

Where/how will the data be made available for reuse?

Data will be available on request after signing a data sharing agreement and only after obtaining informed consent (if applicable, e.g. in case of patient data).

When will the data be made available?

- Upon publication of the research results

Who will be able to access the data and under what conditions?
Data will not be shared, except within the project team collaborators, unless stated otherwise in the study protocol and the applicable informed consent signed by the patients.

What are the expected costs for data sharing? How will the costs be covered?
No additional costs for data sharing

8. Responsibilities

Who will be responsible for data documentation & metadata?
Pieter Schellekens

Who will be responsible for data storage & back up during the project?
Pieter Schellekens

Who will be responsible for ensuring data preservation and reuse ?
Prof. Dr. Bert Bammens

Who bears the end responsibility for updating & implementing this DMP?
The PI bears the end responsibility of updating & implementing this DMP.