DMP title

Project Name DMP_nKPC

Project Identifier C24M/21/035

Grant Title C24M/21/035

Principal Investigator / Researcher NoÃ«l Knops

Project Data Contact fanny.oliveiraarcolino@kuleuven.be

Description The goal of this project is to investigate the potential of specific stem cells (nKSPCs) as a tool for kidney-targeted cell therapy. In order to reach this goal, we: 1. Explore in vitro the immunomodulatory and immunogenic responses of these nKSPCs; 2. Analyse in vitro the regenerative effects of nKSPCs in direct and indirect contact with human kidney tissue and unravel the involved mechanisms; 3. Investigate the immunomodulatory and regenerative effects of nKSPCs therapy leading to improved kidney function in an ex-vivo translational model; 4. Generate and validate clinical grade nKSPCs for clinical application as tool for human kidney-targeted cell therapy.

Institution KU Leuven

1. Data Description

What data will you collect or create? Fill out the table below and/or describe.

Type of data	Format	Volume	How created?
Experimental data Work Package 1 (WP1)	Numerical and text stored in databases in Microsoft Excel (.xlsx), GraphPad (.pzfx files), FlowJo (.fcs and.wsp files) and in text format (as reports, papers in MS word).	5-10 Gb	Experimental procedures with stem cells: FACS, MLR, enzyme activity, actin polymerization, ROS production and quantification of phagocytosis
Experimental data WP2 and 3	Numerical and text stored in databases in Microsoft Excel (.xlsx), GraphPad (.pzfx files), FlowJo (.fcs and.wsp files) and in text format (as reports, papers in MS word). Microscopic images are stored as confocal images (.czi files) or in Image J (as TIFF or JPEG images). RNA-seq data is stored as .fq and .fastq files and metabolomics data as .mzTab and .txt.	100-200 TB	Experimental procedures with stem cells: Fluorescent and confocal microscopic images, electron microscopy, data from molecular biology experiments (qPCR, WB images, ELISAs, cytokine measurements), data from flow cytometry analysis, data from LC-MS/MS analysis, RNA-sequencing, metabolomics data.
Experimental data WP4	Numerical and text data stored in databases in Microsoft Excel (.xlsx), Access file (.mdb), GraphPad (.pzfx files), FlowJo (.fcs and.wsp files), and in text format (list of samples, reports, papers in MS word). Microscopic images are analyzed in Image J (as TIFF or JPEG images). RNA-seq data is stored as .fq and .fastq files.	10 - 100 Gb	Experimental procedures with stem cells: Protein lysates and RNA samples (qPCR, WB images, ELISAs, cytokine measurements), microscopy images, RNA-seq

Do you intend to reuse existing data?

No, we will generate new data.

Do you use personal data (i.e. all data possibly identifying an individual)?

- No

We will isolate nKSPCs from urine of preterm neonates upon signature of the informed consent form by the parents. Samples are pseudonymized , i.e we only receive a code per sample, with date of birth and gender, the identification-code is kept by the Neonatology department. We will use PBMCs from buffy coat of healthy subjects, samples are also pseudonymized.

Human kidney tissue and allografts are from deceased donors.

2. Documentation and Metadata

Describe the documentation that will be created for the data. This section deals with

the way in which you will document how the dataset was created and subsequently processed.

Standard experimental procedures (SOPs) and practices will be fully documented as word (and PDF) and saved on the J-drive database.

Raw experimental data will be collected per experimental test, which will correlate to a text file containing the experimental design, the goal of the experiment, the origin of the samples, instrument settings, the analysis and the conclusion (all necessary information for an independent analyst to use or reuse the data accurately and efficiently).

The same description will be documented in notebooks (with page numbers), as well as in electronic format at the J-drive (word files).

The name of the folder will always contain the date, name of the experiment, and the name of the person who performed the experiment.

Describe the metadata for the data. This section deals with metadata: information contained in your dataset about the research data.

The type of metadata is:

Microscopic images: *date and time, camera model, camera settings, resolution.*

qPCR : spreadsheets with title, description, format

Rna-seq: Gene Expression Omnibus (GEO)

Immunoassays: *spreadsheets with title, description, format*

FACS: descriptions of the specimens and reagents included in the FCM experiment, the configuration of the instrument used to perform the assays and the data processing approaches used to interpret the primary output data (MyFlowCit guidelines)

We will use the repository of KU Leuven for storage of metadata, but in case there are problems we will use Zenodo

3. Ethical, Legal and Privacy Issues

Are there any ethical issues concerning the creation and/or use of the data?

For the establishment of new nKSPC lines the ethics committee of UZ Leuven have approved the protocol under the study number S61919 (Belgisch nummer B3222020000170). An amendment will be necessary for development of cell lines under cGMP conditions with finality of clinical use.

Human kidney tissue and allografts will be obtained from donated kidneys deemed not suitable for transplantation at the UZ Leuven Nephrology and Transplantation Units. Of note, according to the Belgian law of 1986, deceased donation follows the “opt-out” system and approval of an ethics committee for research use of deceased organs is dispensable.

Did you consider all issues about copyrights and IPR?

One of the major goals of our project is to fully characterize nKSPC and establish cGMP production protocols to generate nKSPC for clinical application. This might allow us to start clinical trials using nKSPC and develop relationships with pharmaceutical companies to bring nKSPC to the clinic.

We are in contact with the LRD team (Annelies Beckers and Julien Compagnon) to ensure the valorisation and IP of our research are properly managed from the beginning of its development.

Are the collected data considered to be â€œdata containing personal informationâ€ and are all the requirements about the collection of these data met?

see previous answer:

We will isolate nKSPCs from urine of preterm neonates upon signature of the informed consent form by the parents. Samples are pseudonymized , i.e we only receive a code per sample, with date of birth and gender, the identification-code is kept by the Neonatology department. We will use PBMCs from buffy coat of healthy subjects, samples are also pseudonymized.

Human kidney tissue and allografts are from deceased donors.

4. Data storage and Backup during Research

How and where will the data be stored during research?

- Centrally on storage facilities of the research unit
- Centrally on storage facilities of the university

Cell lines and samples databases are stored as excel or access files in the KU Leuven J-drive. Digital files of research data (raw data, figures, excel files, text files, analysis, microscopy images) will be stored on local KU Leuven PCs, and will be backed up on the shared KU Leuven J-drive. Images from confocal microscopy and RNA-seq will be saved on external hard drives, which are stored in our lab.

Raw experimental data will be collected per experimental test, which will correlate to a text file containing the experimental design, the goal of the experiment, the origin of the samples, the analysis and the conclusion (all necessary information for an independent analyst to use or reuse the data accurately and efficiently).

The same description will be documented in notebooks (with page numbers), as well as in electronic format at the J-drive (word files). Finalized paper notebooks will be kept in the office of the PIs

The name of the folder will always contain the date, name of the experiment, and the name of the person who performed the experiment.

Standard experimental procedures (SOPs) and practices will be fully documented as word (and PDF) and saved on the J-drive database.

Which back-up procedures are in place?

A daily automatic back-up procedure is in place for all data stored on the shared KU Leuven J-drive.

Back-ups of very heavy files such as RNA-seq data will be saved by the user immediately on hard drives

Describe the data security procedures and who has access to the data.

For paper notebooks: Office doors are always locked when researchers are out of the office. In the lab, all doors have a badge-control.

For digital files: all data on J-drive are password protected and it is only accessible for current members of the team.

5. Data selection and Preservation after Research

What is the long-term preservation plan for these dataset(s)?

All data will be stored on the central server of KU Leuven, and will be kept for at least 10 years after the end of the research project, a PhD thesis or a publication.

Data Selection: Which data will have long time value for the research and will be preserved?

Raw data and the subsequent analysis that has lead to any type of scientific publication will be selected for long-time preservation.

6. Data Sharing

Are there any restrictions for sharing the data?

No

If there are no restrictions, which mechanisms will be in place to assure that the data are discoverable, accessible and intelligible?

As mentioned earlier:

Raw experimental data will be collected per experimental test, which will correlate to a text file containing the experimental design, the goal of the experiment, the origin of the samples, the analysis and the conclusion (all necessary information for an independent analyst to use or reuse the data accurately and efficiently).

The same description will be documented in notebooks (with page numbers), as well as in electronic format at the J-drive (word files).

The name of the folder will always contain the date, name of the experiment, and the name of the person who performed the experiment

How will you share the data?

- Repository

- Publication

We plan to publish the data in Open Access Journals, but also the manuscripts will be available through Lirias, taking into account the possible embargo period for the specific journals.
Other data will be made available through the open repository from the moment of publication

With whom will the data be shared?

- Open Data

Published data will be available to everyone.
Experimental data and biological samples will be available only for members of the research team (or on request)

7. Responsabilities and Resources

Who is responsible for Data Management during the project? This will be the person who might receive questions on the data management aspects of the research project.

The promoter (Prof. Noël Knops) bears the end responsibility of updating & implementing this DMP.
Post-docs, PhDs and technicians will have the daily responsibility of record keeping of all data (digital, paper and biological samples). They will also be responsible for a correct and accurate data entry and recording of metadata.

Which additional resources are needed for the execution of the Data Management Plan?

No additional training, equipment or software is currently needed. Costs are coverd by the projects bench fee and we do not expect any additional costs associated with data management, except the publication costs.

Did you read the KU Leuven Data Management Policy? (find the link to the policy in the guidance).

- Yes