G073522N - Peter Hespel

Project Name Peter Hespel (FWO DMP) - G073522N - G073522N - Peter Hespel

Project Identifier DMP_G073522N

Grant Title G073522N

Principal Investigator / Researcher Peter Hespel

Project Data Contact Chiel PoffÃ© - +3216377907- chiel.poffe@kuleuven.be

Description The research project has to be considered both from the perspective of basic research and translational research. The project comprises 3 placebo-controlled clinical trials (CT) and aims to investigate the potential of intermittent exogenous ketosis (IEK) as a novel strategy to improve hypoxic tolerance and adaptation in healthy volunteers. In CT1, we ingestigate the acute effects of IEK during exercise. In CT2, we study the acute effects of IEK on sleep quality in hypoxia following strenuous exercise. In CT3 we scrutinize functional and physiological adaptations as well as acute mountain sickness development during 10 days of hypoxic residence. These data are acquired to investigate the intended research questions and to allow publication in high-impact journals.

Institution KU Leuven

1. General Information

Name applicant

Peter Hespel

FWO Project Number & Title

G073522N - Intermittent exogenous ketosis: a novel strategy to improve hypoxic tolerance and adaptation

Affiliation

- KU Leuven

2. Data description

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

- Generate new 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).

Venous blood samples	Venous blood samples (5ml/sample)	394 venous blood samples	394 venous blood samples will be collected during the clinical trials that are included in this project
Elisa results	.xls	1 GB	Elisa analyses of venous blood samples from healthy volunteers
Heart rate data	.gpx	3 GB	Heart rate data from healthy volunteers
Oxygenation data	.xls	12 GB	Cerebral and muscle oxygenation status from healthy volunteers
Polysomnography data	.mat	25 GB	EEG recordings of healthy volunteers during sleep.
Numeric data (exercise performance, questionnaires, dietary intake, results of biochemical analyses)	.xls	20 GB	Three human clinical trials involving normobaric hypoxia.

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: G-2020-2180-R2(AMD)
Short description of the kind of personal data that will be used: age, gender, weight, height, telephone number, e-mail address, health data (sleep data, blood flow, exercise performance parameters and muscular function), metabolites and hormones in the blood (ketone concentrations, glucose, lactate, oxidative stress and antioxidant capacity, VEGF).

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

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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. Biochemical analyses (elisa). The methodology and protocol will be described in detail in the lab book. The following information will be noted: capture settings, amount of sample loaded, elisa kits with inclusion of standards and controls and antibodies (company and #).
1. Blood samples. The samples will be stored according to the policy of the UZ / KU Leuven biobank.
3. All in-vivo measurements (polysomnography, oxygenation data, heart rate, questionnaires, exercise performance, functional performance). Details on the testing procedures (protocol, climate conditions) and the measurements (devices, date, time) will be described in detail in a .xls file.

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.

- Yes

- Statistical analyses: metadata of database in SPSS
- For each clinical trial one general .xls file will be generated including all data.

5. Data storage and backup during the FWO project

Where will the data be stored?

We will anonymize the data of all clinical trials. The anonymization file will be stored on the personal OneDrive of Prof. Peter Hespel. All data files will be stored on a shared OneDrive (shared between Prof. Peter Hespel, Dr. Chiel Poffé and Drs. Myrthe Stalmans). These files will be time-stamped.

How is backup of the data provided?

The data will also be stored on the shared drive (I drive) of the research group which is secured and automatically backed-up on a daily basis by the ICT services at the department.

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

There is currently 1813 GB free space on our OneDrive and 0.92 TB on the shared I drive.

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

No expected costs. We will use the OneDrive and the I folder which are both provided at no cost by the institution (KU Leuven).

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

The OneDrive and I drive are only accessible for the designated persons.

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 data will be retained for a period of 10 years after the end of the project.

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 10 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 central server is accessible at no cost.

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)?

- No

Which data will be made available after the end of the project?
Anonymized data will be made available upon reasonable request to Prof. Peter Hespel.

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

Data will be available on request after signing a data sharing agreement.

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?
All raw data are available for everyone upon reasonable request.

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

8. Responsibilities

Who will be responsible for data documentation & metadata?
Prof. Peter Hespel

Who will be responsible for data storage & back up during the project?
Prof. Peter Hespel

Who will be responsible for ensuring data preservation and reuse ?
Prof. Peter Hespel

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