DMP title

Project Name GPR 18 as novel target to treat visceral pain

Project Identifier C3/21/039

Principal Investigator / Researcher Guy Boeckxstaens

Description Visceral pain is a hallmark symptom of the irritable bowel syndrome (IBS) for which no efficient treatment is available. It results from sensitisation of TRP (transient receptor potential) channels located on visceral afferent nerves, a phenomenon mediated by histamine released by mast cells. Histamine 1 receptor antagonism blocks TRP sensitisation and improves symptoms in 50% of IBS patients. As TRP channels are also sensitised by other mast cell mediators, therapeutic success will be further improved by intervening with the intracellular mechanism involved in TRP sensitization, an approach that is independent of the initiating trigger. Recently, we showed that resolvin D2 could be an interesting candidate; it prevents and reverses histamine-induced TRPV1 sensitisation via activation of its receptor GPR18, an inhibitory G protein coupled receptor. In this project, we want to further explore the therapeutic potential of GPR18 agonists. These insights are critical for our understanding of IBS and for development of novel treatment modalities.

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?
Calcium imaging data	.sav, .csv, .mdb, .xlsx	1 GB	Microscopy - regions of interest
EMG recordings	.ldb, .xlsx	150 MB	Integration of EMG signals recorded from abdominal muscles
patient characteristics	xlxs	1MB	observational data collected from questionnaires

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)?

- Yes

We will use patient samples/information (biopsies, questionnaires). The information is coded, i.e. each patient or healthy volunteer receives a unique code in order to pseudonimize the collected information. The questionnaires will collect information on demographics, previous history, psychological factors, and symptoms. The strategy to guarantee the privacy of individuals that consented to participate in the study has been approved by the Ethical Committee of UZ Leuven.

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.

Each experiment is registered in the lab journal of the scientist performing the respective experiment. Standard operation procedures (SOPs) have been written for all the techniques used in the lab. Data obtained from a study protocol / series of experiments will be stored in a folder that also contains a readme.txt file explaining the design/protocol, results and labels used in the data analysis file, and a reference to the lab journal of that particular experiment. Also the method of analysis will be described. The information provided will allow another researcher to follow all steps in the data processing.

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

Microscopic metadata will be generated using the OME-TIFF or OXE-XML standard (www.fairsharing.org).

3. Ethical, Legal and Privacy Issues

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

Ethical approval to perform the animal experiments has been obtained on September 16th 2021

(P106/2021).

Did you consider all issues about copyrights and IPR?

Yes. If GPR18 is indeed a target to treat visceral pain, new compounds acting on this receptor could result in novel IP. This will be checked with LRD-KUL.

With respect to patient data and physical samples: patient privacy is respected (see above) and permission to share data / samples is obtained in the informed consents.

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

We will use patient samples/information (biopsies, questionnaires). The information is coded, i.e. each patient or healthy volunteer receives a unique code in order to pseudonimize the collected information. The questionnaires will collect information on demographics, previous history, psychological factors, and symptoms. The strategy to guarantee the privacy of individuals that consented to participate in the study has been approved by the Ethical Committee of UZ Leuven.

Ethical approval has been obtained to perform the experiments described in this project from the Medical Ethics Committee University Hospitals Leuven (human) and the Animal Ethics Committee KU Leuven (P106/2021).

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

Which back-up procedures are in place?

Data will be stored on servers centrally managed by ICTS KU Leuven and with back-up capacities (KU Leuven enterprise box, Largevolume-storage).

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

Access to the J drive is only possible for registered KUL personnel.

Once included, the identity of the patients is encoded, i.e. a unique number is used (hospital patient number) which is coupled to a unique CRF (case report form) number. Only the PI has access to the list of participating subjects (hospital ID, no patient names) and the corresponding CRF number. As such, utmost care is introduced to guarantee the privacy of the patients. The Ethical Committee of UZ Leuven is particularly inquiring on this topic before approving a clinical study and carefully checks this procedure, according to the national and EU legislation.

Files are stored on the J drive of KU Leuven which is protected via a central login for KUL personnel. The file containing the link between the CRF number and the patient’s identity is safed in a dedicated folder on the J drive which is only accessible by the PI and trial nurse via an entrance code. In case data are stored on managed laptops, the hard drive is encrypted.

5. Data selection and Preservation after Research

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

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.

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

All data will be retained during 5 years following the end of the project. Pseudonomized data and physical data will also be stored for longer than 5 years. Permission is requested in the informed consents.

6. Data Sharing

Are there any restrictions for sharing the data?

Yes, due to IP.

With respect to patient data and physical samples: patient privacy is respected and permission to share data / samples is obtained in the informed consents.

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

NA

How will you share the data?

- Publication

With whom will the data be shared?

- On request with peers only

Data will be shared within the research unit. Data under IP will not be shared with peers. Data without sharing restrictions will be shared through peer reviewed publications.

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.

Question not answered.

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

not applicable

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

- Yes