FOOD-INDUCED DUODENAL IMMUNE ACTIVATION: SYMPTOM TRIGGER AND THERAPEUTIC TARGET IN FUNCTIONAL DYSPEPSIA

A Data Management Plan created using DMPonline.be

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Project abstract:

Functional dyspepsia (FD) affects 7.2% of the adult population and has a significant impact on quality of life. Patients present with symptoms in the epigastrium, which include early satiation, postprandial fullness and epigastric pain or burning. Routine investigations including endoscopy are macroscopically normal. Gastric abnormalities, including delayed emptying, gastric hypersensitivity and impaired accommodation, have been implicated in symptom generation. Current treatment options target gastric function, but have limited efficacy. Recent studies have shown low-grade duodenal inflammation characterized by eosinophil and mast cell influx and impaired mucosal integrity in FD. We will investigate the link between duodenal immune activation on the one hand and gastric sensorimotor dysfunction and symptoms on the other hand. We will provide proof of concept for the pivotal role of mast cells through a controlled trial with palmitoyletahnolamide, an endogenous mast cell stabilizing agent with lower levels in FD. We hypothesize that food is the trigger for activation of mast cells through a non-IgE-dependent pathway in the presence of impaired duodenal mucosal integrity. This will be studied in a sham-controlled dietary elimination trial of trigger nutrients, identified by duodenal confocal laser endomicroscopic evaluation of food allergies. If confirmed, our project will reshape the disease concept and management in this prevalent condition.

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DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

Question not answered.

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GDPR

GDPR

Have you registered personal data processing activities for this project?

Question not answered.

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Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

Question not answered.

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

Question not answered.

What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

Question not answered.

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

Question not answered.

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

Question not answered.

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FWO DMP (Flemish Standard DMP)

1. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
		Please choose from the following options: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Aim1. Cross-sectional FD cohort from Aim 2-4	Symptom questionnaires, quality of life questionnaires, psychosocial co-morbidity questionnaires, food frequency questionnaires	New	D	Textual, observational	Redcap file, .txt, .xls	<1Gb	Questionnaires are filled out on the Redcap platform. Data can be extractes as .txt files which are converted into .xls files.
	Personal data: sex, weight, age, length, medication, allergies, co-morbidities	New	D	Textual, observational	Redcap file, .txt, .xls	<100MB	Items are filled out on the Redcap platform. Data can be extractes as .txt files which are converted into .xls files.

	Duodenal biopsies	New	Physical, DIgital	Other: Biopsies obtained during endoscopy, light and immunofluorescence microscopy	Physical slides, tissue blocks and .tif; .czi	<1TB	Histology slides from duodenal biopsies. Widefield images from the Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in Imagej software renders new .tif files. Immunofluorescence images qcuqird with a LSM880 eiss microscope are saved as .ci files using Zeiss Black software. Processing in ImageJ software renders .tif files.
	Gene expression data	New	Physical, DIgital	Other: observational/experimental	Physical, and .txt, .xls files	<1TB	Samples with reaction mix are transferred into 96-well-plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. Graphical overviews of PCR efficacy ar saved as .png files. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID lab in boxes with clear identification on shelves, allocated to Prof. Jan Tack's research unit.

	Protein expression data	New	Physical, DIgital	Other: observational/experimental	Physical, and .txt, .xls files	<1 Tb	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID lab in boxes with clear identification on shelves, allocated to Prof. Jan Tack's research unit.
Aim 2: PEA study (approved as S65406)	Symptom questionnaires, quality of life questionnaires, psychosocial co-morbidity questionnaires, food frequency questionnaires	New	D	Textual, interventional	Redcap file, .txt, .xls	<1Gb	Questionnaires are filled out on the Redcap platform. Data can be extractes as .txt files which are converted into .xls files.
	Duodenal biopsies	New	Physical, DIgital	Other: Biopsies obtained during endoscopy, light and immunofluorescence microscopy	Physical slides, tissue blocks and .tif; .czi	<1 Tb	Histology slides from duodenal biopsies. Widefield images from the Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in Imagej software renders new .tif files. Immunofluorescence images qcuqird with a LSM880 eiss microscope are saved as .ci files using Zeiss Black software. Processing in ImageJ software renders .tif files.
	Personal data: sex, weight, age, length, medication, allergies, co-morbidities	New	D	Textual, observational	Redcap file, .txt, .xls	<100MB	Items are filled out on the Redcap platform. Data can be extractes as .txt files which are converted into .xls files.

	Gene expression data	New	Physical, DIgital	Other: observational/experimental	Physical, and .txt, .xls files	<1 Tb	Samples with reaction mix are transferred into 96-well-plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID lab in boxes with clear identification on shelves, allocated to Prof. Jan Tack's research unit.
	Protein expression data	New	Physical, DIgital	Other: observational/experimental	Physical, and .txt, .xls files	<1 Tb	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID lab in boxes with clear identification on shelves, allocated to Prof. Jan Tack's research unit.
Aim 3: CLEstudy (approved as S65735)	Symptom questionnaires, quality of life questionnaires, psychosocial co-morbidity questionnaires, food frequency questionnaires	New	D	Textual, interventional	Redcap file, .txt, .xls	<100MB	Items are filled out on the Redcap platform. Data can be extractes as .txt files which are converted into .xls files.
	Personal data: sex, weight, age, length, medication, allergies, co-morbidities	New	D	Textual, interventional	Redcap file, .txt, .xls	<100MB	Items are filled out on the Redcap platform. Data can be extractes as .txt files which are converted into .xls files.

	Duodenal biopsies	New	Physical, digital	Other: Biopsies obtained during endoscopy, light and immunofluorescence microscopy	Physical slides, tissue blocks and .tif; .czi	<1 Tb	Histology slides from duodenal biopsies. Widefield images from the Olympus microscope are saved as .tif files using Adobe Photoshop. Processing in Imagej software renders new .tif files. Immunofluorescence images qcuqird with a LSM880 eiss microscope are saved as .ci files using Zeiss Black software. Processing in ImageJ software renders .tif files.
	Gene expression data	New	Physical, digital	Other: observational/experimental	Physical, and .txt, .xls files	<1 Tb	Samples with reaction mix are transferred into 96-well-plates, analyzed in a light-cycler PCR machine. The machine generates a .txt file with the Ct values, which is then transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID lab in boxes with clear identification on shelves, allocated to Prof. Jan Tack's research unit.
	Protein expression data	New	Physical, digital	Other: observational/experimenta	Physical, and .txt, .xls files	<1 Tb	Samples are analyzed in a multiplexing imager. A .txt file with the spectrophotometry results is generated and transferred to an .xls file for further processing. The physical samples (RNA and cDNA) are stored in the freezer of the TARGID lab in boxes with clear identification on shelves, allocated to Prof. Jan Tack's research unit.

Aim 4: diet trial (also approved as S65735)	Symptom questionnaires, quality of life questionnaires, psychosocial co-morbidity questionnaires, food frequency questionnaires	New	D	Textual, interventional	Redcap file, .txt, .xls	<100MB	Items are filled out on the Redcap platform. Data can be extractes as .txt files which are converted into .xls files.
	Personal data: sex, weight, age, length, medication, allergies, co-morbidities	New	D	Textual, interventional	Redcap file, .txt, .xls	<100MB	Items are filled out on the Redcap platform. Data can be extractes as .txt files which are converted into .xls files.

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

Not applicable

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

Reference to several ethical committee approvals (including GDPR questionnaire if applicable): S57826, S56978, S64291, S65406, S54735

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

General description of the kind of personal data that will be used and their handling: All data will be used as pseudoniminized data. THe file containing the link between the unique study number and the patient or subject ID (as used in the electronic patient file) and the name of the patient or subject is pasword protected and stroed on the secrue server of the UZ Leuven. This file also contains the contact details including e-mail and telephone number.
Data collected as pseudoniminzed data: age, sex, weight, length, medication, allergies, co-morbidities, medical history, symptom severity and frequency, food intake, responses to questionnaires regarding quality of life and co-morbidity.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements/ research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

2. Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).

All protocols (docx.file) and accompanying result files (.xlsx,.tif files) containing the key to identify the experimental samples are available on a shared drive from our lab
managed by the KU Leuven and/or UZ Leuven. Only members from the team have access to these folders.
All ethical documents are available on the shared drive from the research groups involved.
An overview of the samples stored in the biobank is available on the shared drive from our research group.
For the microscopic image data that will be recorded: recording parameters (powers, excitation and emission wavelength), dimensions, image type, bit-depth, pixel sizes
and microscope settings, will be stored. Either in a metafile accompanying the data (with identical filename) or embedded in the tiff header.
The experimental protocols, stimulation settings, temperatures of the physiological experiments that will be performed during this projected will be described in detail in a
lab book and referred in a ReadMe text file that will accompany the recorded data. Similarly for the processed and analyzed data, all parameters used to arrive to the
results are stored within the image format.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- No

Metadata standards are typically not used within our lab group. We do have a minimal set of requirements that will be followed in order to ensure standardization and
possibility to reinterpret and reuse the data when necessary and permitted.
For the microscopic imaging data we do adhere to metadata standards:
Images will be stored in *.ome tiff format, which enables storing a multitude of microscope and recording parameters. For the more experimental imaging paradigms for
which actual changes are made to the instrumentation, the metadata will be stored in accompanying txt or csv files.

3. Data storage & back-up during the research project

Where will the data be stored?

All generated data are stored on the shared network drive platforms of the KU Leuven and UZ Leuven that are only accessible to the members of the research teams
(only for PhD, postdocs, technicians not for master students). Big files such as images are stored on the sharepoint online drives.
Microscopy data: All original recordings and their metadata will be stored in one copy on external harddrives, which will be labeled by projectname, subproject,
experiment, data and experimenter initials.
The images that are judged of sufficient quality to derive conclusive data, will be analysed as saved on the researcher’s computer with a backup either on a local external harddrive or via the LUNA network. Exchange of data between will happen via the LUNA network, which keeps track of versions and assures safe backups.

How will the data be backed up?

Backup is secured daily on servers of the University and the University Hospital.

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

The group has sufficient data storage capacity available.

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Only the PIs are authorized to give access to the members of his/her team to the shared drives of the KU Leuven and/or the UZ Leuven.

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

The costs are considered to be budgeted within the working cost items of the project.

4. Data preservation after the end of the research project

Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

All data will be preserved for 10 years according to KU Leuven RDM policy
All data will be preserved for 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on
humans

Where will these data be archived (stored and curated for the long-term)?

Large Volume Storage (longterm for large volumes)
KU Leuven RDR
Data will be stored on archive drives of the university.

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

These costs are considered to be budgeted within the work costs of the project and maintained for longer duration by the PIs after the end of the project.

5. Data sharing and reuse

Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.

- Yes, in a restricted access repository (after approval, institutional access only, …)

Yes, as restricted data (upon approval, or institutional access only)
Anonimized data can be made available for further analyses in line with the terms of the ICFs and following advice from the relevant local ethics committees.

If access is restricted, please specify who will be able to access the data and under what conditions.

The anonimized data sets can be shared within the TARGID research unit or shared upon request. In such case, data will be available after signing a data sharing
agreement.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain in the comment section per dataset or data type where appropriate.

- No

no restrictive factors.

Where will the data be made available? If already known, please provide a repository per dataset or data type.

A specific repository will be chosen after the publication strategy is known as some journal request specific repositories.

When will the data be made available?

Only after publication of the research results in a peer-reviewed journal.

Which data usage licenses are you going to provide? If none, please explain why.

Data usage licences will be discussed with LRD before any licences are granted.
Similarly, when DTAs or MTAs are discussed, this will always be after consulting and collaborating with LRD

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- Yes

Depending on the data repository and the type of data that would be made available, a unique identifier will be added to the data set.

What are the expected costs for data sharing? How will these costs be covered?

If shipment of data or material is required by an other study group abroad, after approval the costs of drafting of MTA/DTA and shipment itself will be covered by the
requesting party.
Exchange of microscopic imaging data can be done via BELNET and no extra cost.

6. Responsibilities

Who will manage data documentation and metadata during the research project?

Researchers who generate the data

Who will manage data storage and backup during the research project?

Researchers who generate the data

Who will manage data preservation and sharing?

Researchers who generate the data

Who will update and implement this DMP?

Jan Tack