Plan Overview

A Data Management Plan created using DMPonline.be

Title: Management of (gestational) diabetes in pregnancy: new insights in predictors, complications, technology, and prevention of the long-term metabolic risk postpartum

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Principal Investigator: Katrien Fouzia Benhalima

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Template: FWO DMP (Flemish Standard DMP)

Principal Investigator: Katrien Fouzia Benhalima

Project abstract:

Diabetes and gestational diabetes (GDM) are associated with increased risks for pregnancy complications. Women with a history of GDM are also at increased risk to develop type 2 diabetes (T2D). Pregnant women with a history of bariatric surgery are at increased risk for fetal growth restriction. Studies are therefore needed to investigate predictors, novel therapies and preventive strategies postpartum in these high risk populations. In this research project we will therefore investigate predictors (clinical and novel biomarkers) for long-term metabolic risk and adherence to a mobile-based lifestyle intervention in women with a history of GDM. Secondly, with a large multicentric RCT we will investigate whether the addition of a GLP-1 agonist (semaglutide) on top of lifestyle measures, can reduce the risk to develop T2D in women with prediabetes after a history of GDM. Thirdly, we will investigate whether the use of glucose sensors can improve pregnancy outcomes in women with GDM. Fourthly, we will investigate the safety and effectiveness of an artificial pancreas during delivery in women with T1D and predictors for glycaemic control in pregnancy. In addition, we will evaluate whether an adapted artificial pancreas (based on the CRISTAL RCT we performed) can further improve glycaemic control in pregnancy. Lastly, we will investigate the association between glucose metabolism and metabolomics with fetal growth restriction in pregnant women with a history of bariatric surgery.

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Management of (gestational) diabetes in pregnancy: new insights in predictors, complications, technology, and prevention of the long-term metabolic risk postpartum

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)

We will collect data from clinical measurements (such as height, weight, BMI and blood pressure), laboratory measurements (such as oral glucose tolerance tests and fasting analyzes), Novel biomarkers (metabolomics and glycated CD59), data derived from insulin pump therapy and glucose sensors (such as insulin dosage and glucose measurements), and self-administered questionnaires (completed by participants during the study visits online). Redcap will used as database.
The data will be stored in the university's secure environment for private data. Only personnel working on the study, has access to the study through Redcap.

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)

- Designation of responsible person (If already designated, please fill in their name.): Hilde Morobé, head of clinical trial team of endocrinology UZ Leuven
- Storage capacity/repository
  - during the research: storage will done in each participating center
  - after the research: Long-term storage of data during at least 25 years, will be done in collaboration with OASIS (https://www.oasisgroup.com/).

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)

NA

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)

NA

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

NA

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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
CRISTAL	Completed RCT of 780G system in pregnancy	• Reuse existing data	• Digital	• Observational • Experimental • Compiled/aggregated data • Simulation data	• .xml, .tab, .csv,.pdf, .txt,	• <1GB	
Melinda	Completed RCT-Mobile-based lifestyle intervention	• Reuse existing data	• Digital	• Observational • Experimental • Compiled/aggregated data	xml, .tab, .csv,.pdf, .txt,	• <1GB	
BEDIP-FUS	Completed bservational follow-up study	• Reuse existing data	• Digital	• Observational • Experimental • Compiled/aggregated dat	xml, .tab, .csv,.pdf, .txt,	• <1GB	
SERENA	Ongoing RCT with semaglutide for the prevention of diabetes after gestational diabetes	• Generate new data	• Digital	• Observational • Experimental	xml, .tab, .csv,.pdf, .txt,	• <1GB	
CORDELIA	Ongoing RCT on continuous glucose monitoring in women with gestational diabetes	• Generate new data	• Digital	• Observational • Experimental	xml, .tab, .csv,.pdf, .txt,	• <1GB	
GLORIA	ongoing observational study with continuous glucose monitoring in pregnant women with a history of bariatric surgery	• Generate new data	• Digital	• Observational • Experimental	xml, .tab, .csv,.pdf, .txt,	• <1GB	

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:

Re-use of data, is applicable to data of studies (CRISTAL, Melinda and BEDIP-FUS studies) that have been completed and from which subanalyzes are performed: Mobile-based lifestyle intervention in women with glucose intolerance after gestational diabetes mellitus (MELINDA): a multicenter randomized controlled trial. Caro Minschart, Nele Myngheer, Toon Maes, Christophe De Block, Inge Van Pottelbergh, Pascale Abrams MD, Wouter Vinck, Liesbeth Leuridan, Sabien Driessens, Chantal Mathieu, Jaak Billen, Christophe Matthys, Annouschka Laenen, Annick Bogaerts and Katrien Benhalima. EClinicalMedicine. 2024 Mar 8;70:102523. doi: 10.1016/j.eclinm.2024.102523. eCollection 2024 Apr;

Comparing advanced hybrid closed loop therapy and standard insulin therapy in pregnant women with type 1 diabetes (CRISTAL): a prospective, multicentre, randomized controlled trial. Katrien Benhalima, Kaat Beunen, Nancy Van Wilder, Dominique Ballaux, Gerd Vanhaverbeke, Youri Taes, Xavier-Philippe Aers, Frank Nobels, Joke Marlier, Dahae Lee, Joke Cuypers, Vanessa Preumont, Sarah E. Siegelaar, Rebecca C. Painter, Annouschka Laenen, Pieter Gillard, Chantal Mathieu. Lancet Diabetes Endocrinol 2024 Lancet Diabetes Endocrinol 2024 Published Online April 29, 2024 https://doi.org/10.1016/ S2213-8587(24)00089-5,

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

All studies have received EC approval before the start of any study-related acitivity.

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

Privacy Registry Reference: E-2022-3173. GDPR questionnaire is completed at the time of EC submission
Short description of the kind of personal data that will be used: **regular personal data** Date/year of birth and/or age, Initials, personal identification number assigned to data subjects participating in the study such as EAD number, socio-economic data such as ethnicity, job, education and income **Specify special/sensitive categories of personal data** Health data (e.g. description of characteristics of physical features of the body, medical history and medical test information (such as blood samples)
Whose personal data are being processed for the purpose of the research (in accordance with the protocol)? Patients of UZ Leuven, Patients of the other participating hospitals

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.

- Yes

Data from the CRISTAL study might be used for simulation by the compagny Medtronic to see if the algorithm of the 780G Minimed insulin pump can be improved for pregnancy. Data-transfert (pseudonymised digital data with data on glycaemic profiles of continuous glucose monitoring, duration of pregnancy and weight) with LRD has been established and has been transfered to Medtronic.

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).

For the food diary and questionnaire data, a codebook will be generated containing study design and methodology. For the clinical examinations, details on the setting of the examinations (SOP's) will be documented in a Word document. Also steps taken to remove direct identifiers in the data will be described.
For the lab analyzes and performing the OGTT's, details on the type of analyzes (units and normal lab values) and SOP on performing OGTT's , will be documented in a word document.
For the continuous glucose monitoring (CGM) data, a SOP is provided and ill be documented in a word document.

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

No, for all datasets and types.

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

Where will the data be stored?

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

How will the data be backed up?

The data will be backed up 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

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

Since we will be working with sensitive personal data that are pseudonymised, the data will be stored in the university's secure environment for private data.

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

Storage of data during the study (through Redcap), will come at a limited cost of 80 euro per year. Long-term storage of data in collaboration with OASIS, will come at a cost of about 1500 euro for 25 years. This will be covered by the FWO budget.

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...).

Long-term storage of all data is planned for 25 years (according to legal requirements of the EC).

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

Long-term storage of data will be done with OASIS (contract with UZ Leuven is in place) for at least 25 years.

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

Storage of data during the study (through Redcap), will come at a limited cost of 80 euro per year. Long-term storage of data in collaboration with OASIS, will come at a cost of about 1500 euro for 25 years. This will be covered by the FWO budget.

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, …)

The full dataset will be deposited in a cvs format in KU Leuven RDR under a CC-BY license.

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

The anonymised transcripts will be made available through Harvard Dataverse. Access will be considered after a request is submitted explaining the planned reuse. Only uses for research purposes will be allowed and commercial reuse will be excluded.

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

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

The full dataset will be deposited in a cvs format in KU Leuven RDR under a CC-BY license.

When will the data be made available?

Upon publication of the main research results and upop publication of several subanalyzes of the different studies.

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

KU Leuven RDR under a CC-BY license.

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.

- No

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

No costs are expected.

6. Responsibilities

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

phD students and PI K Benhalima

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

The local investigators in each participating center and for the Redcap database, the PI and phD student.

Who will manage data preservation and sharing?

The PI, Katrien Benhalima.

Who will update and implement this DMP?

The PI, Katrien Benhalima.