Plan Overview

A Data Management Plan created using DMPonline

Title: Dysfunctional voiding: exploring disease transition from childhood to adulthood

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Funder: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

Dysfunctional voiding is a condition characterized by an impaired relaxation of the pelvic floor musculature during voiding. Both the International Continence Society (ICS) as the International Children’s Continence Society (ICCS) use equivalent definitions, wherein the existence of a staccato/intermittent urinary flow is central. To date it is however still not clarified if adult cases are new-onset presentations of DV or persistent childhood complaints. The aim of this study is therefore to explore the development of DV from childhood to adulthood, in order to improve our transitional care and to avoid repeated invasive examination in adults with childhood DV, wherein DV is difficult to based on clinical symptoms solely.

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Dysfunctional voiding: exploring disease transition from childhood to adulthood

1. General features

1.1. Please fill in the table below. When not applicable (yet), please fill in N/A.

DMP template version	29 (don't change)
ABR number *(only for human-related research)*	TBD
METC number *(only for human-related research)*	TBD
DEC number *(only for animal-related research)*	-
Acronym/short study title	DV
Name Research Folder	xx-xxx_DV
Name Division	Surgical Specialties
Name Department	Urologie
Partner Organization	N/A
Start date study	01-06-2021
Planned end date study	30-08-2021
Name of datamanager consulted*	D. Steins
Check date by datamanager	02-03-2021

1.2 Select the specifics that are applicable for your research.

- Clinical study
- Monocenter study
- Prospective study
- WMO
- Use of Questionnaires
- Observational study

We will conduct a cohort-study with cross-sectional follow-up, by approaching the 130 patients that completed the follow-up in the study of Klijn et al. 2006. Based on existing data, the existence of DV will first retrospectively be re-assessed at baseline and after conservative treatment (end of follow-up in the previous study), additionally all participant will be invited for a uroflowmetry with post-void residual assessment at the outpatient clinic of the UMC Utrecht and will receive a digitally questionnaire regarding current LUTS in order to establish the actual existence of DV.

2. Data Collection

2.1 Give a short description of the research data.

The study PI from the study of Klijn et al. will store the original research dataset (.sav file format) in a secure Research Folder Structure from the UMC Utrecht with access control. After informed consent, each study participant will be given a unique identification number, additional study data (flowpatterns + PVR measurement) will be entered to a web based data management application (Castor EDC). This database will be supplemented by the outcome of a questionnaire that will be automatically sent in Castor via an email url-link.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage Space
Human	130 records	eCRF	Castor EDC	Quantitative	.csv	0-10GB
Human	0-130	Questionnaires	Castor EDC	Quantitative	.csv	0-10GB
Human	0-130	Flowpaterns + PVR measurement	Castor EDC	Quantitative	.csv	0-10GB
Human	130 records	Existing data from Klijn et al. 2006	-	Quantitative	.sav	0-10GB

2.2 Do you reuse existing data?

- Yes, please specify

Existing data (.sav) from the study of Klijn et al. 2006 will be re-used.

2.3 Describe who will have access to which data during your study.

An existing data file (.sav) containing personal data from the study of Klijn et al. 2006 will be stored on the secured Research Folder Structure and used by a member of the research team with a care relationship to the patients to establish witch patients can be approached for participation in our study.
Until informed consent is obtained, only investigators with a care relationship to the to the former patients will have access to this data. After informed consent is obtained, a (pseudonymized) data set containing only participant data will be extracted by the data manager.
Using this data will be part of the informed consent procedure for the trial. Study participants will then also be given a unique identification number to ensure confidentiality. Additional study data will be entered in to a web-based data management application (Castor EDC) by members of the research team. This database will be supplemented by the outcome of a validated questionnaire that will be automatically sent via an email url-links (Castor EDC). During the trial, the PI and research personnel will only have acces to the key linking table for prospective data collection and verification procedures. This acces will completely be revoked after completion of inclusion and data collection. From then the key table, linking study specific ID's to patient ID's, will only be available to the datamanager. Statistical analyses will be performed with the pseudonymized data set.

Type of data	Who has access
Direct identifying personal data	Research team with care relationship to patient, Datamanager
Key table linking study specific IDs to Patient IDs	PI (with care relationship to patient), Datamanager
Pseudonymized data	Research team, Datamanager

2.4 Describe how you will take care of good data quality.

Experimental data from patients will be collected in an electronic Case Report Form (eCRF) in a certified Data Capture Tool: Castor. In the eCRF, skips and validation checks are built in. Data quality will be checked by an independent monitor from the DHS monitor pool.

#	Question	Yes	No	N/A
1.	Do you use a certified Data Capture Tool or Electronic Lab Notebook?	X		
2.	Have you built in skips and validation checks?	X		
3.	Do you perform repeated measurements?		X	
4.	Are your devices calibrated?			X
5.	Are your data (partially) checked by others (4 eyes principle)?	X		
6.	Are your data fully up to date?	X		
7.	Do you lock your raw data (frozen dataset)	X		
8.	Do you keep a logging (audit trail) of all changes?	X		
9.	Do you have a policy for handling missing data?	X		
10.	Do you have a policy for handling outliers?	X		

2.5 Specify data management costs and how you plan to cover these costs.

#	Type of costs	Division ("overhead")	Funder	Other (specify)
1.	Time of datamanager	X		
2.	Storage	X		
3.	Data capture tool license fee	X		
4.	Archiving	X		

2.6 State how ownership of the data and intellectual property rights (IPR) to the data will be managed, and which agreements will be or are made.

UMC Utrecht is and remains the owner of all collected data for this study. The data is collected in a relatively large patient group and is very valuable for further, broader studies. It may for example be used to find study subjects for future treatment studies. Our data cannot be protected with IPR, but its value will be taken into account when making our data available to others, when setting up Research Collaborations and when drawing up Data Transfer Agreement(s).

3. Personal data (Data Protection Impact Assessment (DPIA) light)

Will you be using personal data (direct or indirect identifying) from the Electronic Patient Dossier (EPD), DNA, body material, images or any other form of personal data?

- Yes, go to next question

I will process personal data. I have checked the full DPIA checklist and I do not have to complete a full DPIA. I therefore fill out this DPIA light and proceed to 3.1.

3.1 Describe which personal data you are collecting and why you need them.

Which personal data?	Why?
Patient demographics (i.e. age at study inclusion, age at start conservative treatment)	To describe our study populations
Lower urinary tract symptoms (i.e. incontinence, post-voidal residue, urinary tract infections and conservative treatment succes)	To access therapy succes
Email adress	Required for sending questionnaires (Castor)

3.2 What legal right do you have to process personal data?

- Study-specific informed consent

All use of personal data will be part of the trial data collection procedures which are covered by informed consent of subjects.

3.3 Describe how you manage your data to comply to the rights of study participants.

The data are pseudonymized after completing the informed consent procedure and the linking table to personal data is saved.The decision data manager manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data.

Right of Acces	Research data are coded, but can be linked back to personal data, so we can generate a personal record at the moment the person requires that. This needs to be done by an authorized person.
Right of Rectification	The authorized person will give the code for which data have to be rectified.
Right of Objection	We use informed consents.
Right to be Forgotten	In the informed consents we state that the study participant can stop taking part in the research.Removal of collected data from the research database can not be granted because this will result in a research bias.

3.4 Describe the tools and procedures that you use to ensure that only authorized persons have access to personal data.

We use the secured Research Folder Structure and Castor EDC that ensures that only authorized personnel has access to personal data.
Research folder: \\ds\DATA\HS\Onderzoek\Urologie\xx-xxx_DV

3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.

We will not transport any personal data outside the UMCU network drives.

4. Data Storage and Backup

4.1 Describe where you will store your data and documentation during the research.

The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht (protected by permission rights). We will need max 1-3 GB storage space, so the capacity of the network drive will be sufficient.

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

All existing (research) data is directly stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT). During data collection, also automatic backups will be made in the Electronic Data Capture Tool Castor. Upon completion of data collection, all data are exported and aded to the Research Folder Structure (UMC Utrecht networked drives).

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

Extra files will be added to the file structure that contains information about our data. Herein we will describe the major entities in the study, used protocol(s), the origin of the collected data and an overview of the key dates associated with the data (i.e. data modification dates and project start and end date).

5.2 Describe your version control and file naming standards.

File naming will be descriptive and supplemented with an ascending numbering (e.g. Manuscript_V1_FvG_16-10). We will keep track of changes describing changes per datestamp for each file in a separate Word document, that will be stored in our study file structure.

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

A study protocol is written in which we state why we will use which data and which statistical analysis we plan to do in which software. The study protocol will be stored in the project folder, so it is findable and insightful for my peers.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

The data package will contain: the raw (anonymized) data, the study protocol describing the methods and materials, the script to process the data, a codebook with explanations on the variable names, and a ‘read_me.txt’ file with an overview of files included and their content and use.

7.2 Describe for how long the data and documents needed for reproducibility will be available.

In view of the regulation for Clinical Trials, I need to store all data for at least 15 years with the goal to be able to go back to patient level.

7.3 Describe which archive or repository (include the link!) you will use for long-term archiving of your data and whether the repository is certified.

After finishing the project, the data package will stay stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the PI of the research group. When the UMC Utrecht repository is available, the data package will be published here.

7.4 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.

I will be using a DOI-code and will update this plan as soon as I have the code.

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

TBD at the end of this project

8.2 Are there any reasons to make part of the data NOT publicly available or to restrict access to the data once made publicly available?

- Yes (please specify)

TBD at the end of this project

8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.

TBD at the end of this project

8.4 Describe when and for how long the (meta)data will be available for reuse

- (Meta)data will be available upon completion of the project

TBD at the end of this project

8.5 Describe where you will make your data findable and available to others.

TBD at the end of this project