Plan Overview

A Data Management Plan created using DMPonline

Title: Invloed van sedatie bij een hydrostatische redressie bij kinderen met een invaginatie

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Affiliation: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

We want to investigate the effect of sedation on outcome of patients with an ileocolic intersusseption. We will look at the psycological outcome and the succesrate.

ID: 71213

Last modified: 17-02-2021

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Invloed van sedatie bij een hydrostatische redressie bij kinderen met een invaginatie

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)*	
METC number *(only for human-related research)*	2020-0824
DEC number *(only for animal-related research)*	
Acronym/short study title	ISI
Name Research Folder	20-824_ISI
Name Division	Surgery
Name Department	Pediatric Surgery
Partner Organization	
Start date study	1-3-2021
Planned end date study	1-7-2021
Name of datamanager consulted*	Dax Steins
Check date by datamanager	17-02-2021

1.2 Select the specifics that are applicable for your research.

- Multicenter study
- Prospective study
- Non-WMO
- Use of Questionnaires

This is a multicenter study with the Erasmus MC (Rotterdam, Netherlands) as initiating center. UMCU serves as recruiting centrum only.

2. Data Collection

2.1 Give a short description of the research data.

For this multicenter study, we want to examine the influence on procedural sedation on parental satisfaction en the possible psychological impact on parents/caretakers from children who were treated for an ileocolic intersusseption.

We will include all patients, till the age of 16 years, treated for an ileocolic intersusseption in the UMC Utrecht en Erasmus MC from 1 January 2019 until 31? March 2020.

Study duration: 2 years

After informed consent, patients will receive a paper questionnaire? by post?. Additional health care information will be manually extracted from the electronic health records. This includes patient demographics, medical history, **.. patiënten- en procedurele gegevens verzameld worden.** Following data collection, data will be pseudonymized and shared with Erasmus MC via a secure way (SurffileSender or SURFDrive)

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	40	EPD (HiX)	Research Data Platform (RDP)	Quantitative	.xlsx	0-10 GB
Human	40	Paper Questionnaire	Excel?	Quantitative / Qualitative	.xlsx	0-10 GB

2.2 Do you reuse existing data?

- Yes, please specify

In this retrospective study, we use data from HiX and we will use a questionnaire.

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

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.

We do not use a data capture tool, such as Castor. We shall collect our data in an Excel file.

#	**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.	Design of eCRF	X			
3.	Questionnaire license fee	X			
4.	Storage	X			
5.	Archiving	X			
					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.

Erasmus MC is the owner of all collected data for this study.

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?**
Name,, phonenumber and adress of participants	To be able to invite participants for taking part in the research and to send them questionnaires
Demographics	To describe our study population
Data about the intersusseption and the treatmentprotocol	To describe the treatment our patients have recieved

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

- Study-specific informed consent

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

The data are pseudonymized and the linking table to personal data is saved. An authorized person manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data.

Right	**Example answers**
Right of Access	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 consent we state that the study participant can stop taking part in the research. Removal of collected data from the research database cannot be granted because this would 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 that ensures that only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID.

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

1. In case we need to transport personal data with colleagues, we use Surffilesender with encryption.
2. We will have a Research Agreement and/or Data Transfer Agreement with the Erasmus MC. The agreement is in the making.

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. We will need +/- 50 GB storage space, so the capacity of the network drive will be sufficient. Paper dossiers will be stored safely in a locked cabinet in a locked room in the UMC Utrecht. A project specific procedure is in place for access to the paper dossiers. Documentation of this procedure is stored in the Research Folder Structure.

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

All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).

5. Metadata and Documentation

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

For the data collected in Excell, I prepared a codebook of my research database. We do not use metadata standards yet.

5.2 Describe your version control and file naming standards.

We will distinguish versions by indicating the version in the filename of the master copy by adding a code after each edit, for example V1.1 (first number for major versions, last for minor versions). The most recent copy at the master location is always used as the source, and before any editing, this file is saved with the new version code in the filename. The file with the highest code number is the most recent version. Every month, we will move minor versions to a folder OLD. The major versions will be listed in a version document (projxVersDoc.txt), stating the distinguishing elements per listed version.

6. Data Analysis

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

Not Applicable.

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 data, the study protocol describing the methods and materials, the publication, a codebook with explanations on the variable names.

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. This is a non-WMO study.

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.

TBD

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

TBD

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.

Not applicable

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?

Not applicable

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

Not applicable

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

Not applicable

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

Not applicable