Plan Overview

A Data Management Plan created using DMPonline

Title: Prospective assessment of the position of cochlear implants in bilaterally implanted pediatric patients.

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Template: UMC Utrecht DMP

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Project abstract:

Rationale: Cochlear implantation in children is mostly performed bilaterally, either sequentially or simultaneously. The external part of the cochlear implant (CI), the transmitter coil, which attaches to the internal part of the implant through a magnet, can be quite distinguishable. For optimal aesthetic results, the CI surgeon plans the CI position during cochlear implantation to achieve symmetrical placement of the external magnet.

Objective: To assess symmetry of CI placement in bilaterally implanted pediatric patients.

Study design: Prospective observational study.

Study population: Pediatric patients (< 18 years) who underwent bilateral cochlear implantation at the UMC Utrecht, location Wilhelmina Children's Hospital (WKZ).

Main study parameters/endpoints: Assessment of symmetrical placement of the R/S device in bilaterally implanted patients.

Nature and extent of the burden associated with participation, benefit and group relatedness: The burden for children is considered minimal, the measurements and photographs take a few minutes to perform and take place the same day as their regular appointment. Possible benefits for CI surgeons and therefore for CI patients, would be better understanding of the feasibility of drilling a bony well, as well as the risk associated with this surgical technique. Furthermore, assessment of symmetry of placement could increase awareness in CI surgeons of the aesthetic results.

ID: 90170

Start date: 01-01-2022

End date: 30-06-2022

Last modified: 22-04-2022

Prospective assessment of the position of cochlear implants in bilaterally implanted pediatric patients.

1. General features

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

DMP template version	30 (don't change)
ABR number *(only for human-related research)*	N/A
METC number *(only for human-related research)*	N/A
DEC number *(only for animal-related research)*	N/A
Acronym/short study title	SYMMETRICAL
Name Research Folder	xx-xxx_SYMMETRICAL
Name Division	Heelkundige Specialismen
Name Department	KNO
Partner Organization	N/A
Start date study	01-04-2022
Planned end date study	30-07-2022
Name of datamanager consulted*	Nivard Koning
Check date by datamanager	

1.2 Select the specifics that are applicable for your research.

- Non-WMO
- Monocenter study
- Prospective study
- Observational study

For this study prospective acquisition and analysis of data is required.

2. Data Collection

2.1 Give a short description of the research data.

Objective: To assess symmetry of CI placement in bilaterally implanted pediatric patients.

Study population: Pediatric patients (< 18 years old) who have underwent bilateral cochlear implantation at the UMC Utrecht, WKZ and are still in the regular rehabilitation follow up.

Study interentions: The manual measurement data will be filled out on a CRF. These will then be reported in Excel. The photographs will be downloaded and saved in the research folder. The results of the analysis will be reported in an Excel file.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	25	Data from manual measurements	Castor	Quantitative	.cvs	
Human	25	Photographs		Image	.jpeg	
Human	25	Photographs (analysis)	Castor	Quantitative	.cvs	

2.2 Do you reuse existing data?

- No, please specify

For this study we will collect primary data in order to assess the symmetrical placement of the cochlear implants in bilaterally implanted children in our center.

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

Clinical data will be collected from the electronic patient file (Hix). Only the research team members and the datamanager have access to the non-pseudonymized data. The data will be pseudonymized with a study-specific study ID. The research team gets the data extract, pseudonymized.

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	Research team members, Datamanager
Pseudonymized data	Research team, Datamanager

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

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 collection will be frozen before analysis. Versions will be recorded in eLabJournal. Data will be matched by study subject code.

#	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		

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 in Europe. 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?
Age (at implantation), cochlear implant model	To describe our study population
Manual measurements of the implant location	To investigate if the implants are positioned symmetrically in bilateral implanted patients.
Photographs of the head (sides and back) with implants in place.	To investigate if the implants are positioned symmetrically in bilateral implanted patients.

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

- Study-specific informed consent

We acquire study-specific informed consent. The signed consent will enable a right to process specific personal data.

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. The procedure can be found in de RSF. Due to the nature of the study (informed consent cannot be used) we violate the right of access, right of objection, the right to be fogotten and the right of rectification as described in section 8.2 "Recruitment and consent" of our study protocol.

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 the principle investigator (PI) 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.

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. We will need +/- 20 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).
Upon completion of data collection, all data are exported and saved in the Research Folder Structure where they are automatically backed up by the UMC Utrecht backup system.

5. Metadata and Documentation

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

For the data collected in Excel we use metadata standards for the codebook and excel analysis.
Metadata that will be generated are the following:

- Data of the angle calculations as described in section 6.2 of the study protocol.
- Syntax for the data analysis
- Data analysis results
- Publication on the study results.

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.

I will make an overview of datasets and analysis scripts, such that it is fully clear how the statistical analysis is performed.
The analysis plan will be stored in the project folder, so it is findable for my peers. Peers will be

able to repeat the analysis based on my overview.

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 script to process the data, the scripts leading to tables and figures in the publication, 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.

Data and documentation needed to reproduce findings from this non-WMO study will be stored for at least 15 years.

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 be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator 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.

There are no plans to publish the full dataset, however we consider puplishing our metadata in a public repository. If we publish we will publish a PID(DOI) from our publication.
I will update the PID when available.

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.

The raw data can be of interest for other researchers or for spin off projects. Other research teams (national and international) might interested in the future to gather and assess these data for future implementation of obtained outcome after the research is finished.

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)

Our data will be shared with third parties after approval of the Principle Investigator and a DTA with the receiving party. The criteria and time period will be determined on a case-by-case basis.
The publication will be openly accessable. The study protocol and this Data Management Plan will also be available. Along with the publication, the codebook of the data and scripts of analysis in SPSS will be available.

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

After finishing the project the metadata will be available. Data will not be available because of privacy legislation but the metadata will be open. In the event that peers like to reuse our data this can only be granted if the research question is in line with the original research question of our research. Every application therefore will be screened upon this requirement. The criteria and time period will be determined on a case-by-case basis.

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

- (Meta)data will be available as soon as article is published

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

The metadata and pseudonimized data will be made available through DataverseNL.