Plan Overview

A Data Management Plan created using DMPonline

Title: Retrospective review of patient outcomes after pediatric cochlear implantation and analysis of temporal bone thickness.

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Template: UMC Utrecht DMP

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Project abstract:

Rationale: Cochlear implantation in children, especially young infants, can be challenging due to the insufficient skull thickness needed for embedment of the receiver/stimulator (R/S) device. Although this surgical procedure is considered low risk, complications could occur such as migration or extrusion of the R/S device, wound infection or device failure. To our knowledge, the skull thickness in the region of implantation has not yet been assessed in the context of cochlear implantation.

Objective: The aim of this study is to investigate the surgical techniques used in our center for positioning and fixation of the R/S device and placement of the electrode array, and complications and revision surgery in our pediatric CI cohort, to obtain data regarding temporal bone thickness in a pediatric population in order to determine the feasibility of drilling a bony well.

Study design: The proposed study has two phases that both are retrospective cohort studies.

Study population: First phase: Clinical data from pediatric patients who underwent unilateral or bilateral cochlear implantation at the UMC Utrecht, location Wilhelmina Children's Hospital (WKZ) from 01-01-1996 until 31-03-2021. Second phase: Imaging data from 200 pediatric patients regardless of indication who underwent CT-scan of the temporal bone in the UMC Utrecht in 01-01-2021 until 31-12-2021 .

Main study parameters/endpoints: The main study endpoints for each phase are: (I) the complications and revisions after CI surgery, (II) the feasibility of drilling a bony well in the temporal bone for R/S device fixation.

Nature and extent of the burden associated with participation, benefit and group relatedness: Due to the retrospective design of the phases, there is no burden with participation.

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End date: 30-06-2022

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Copyright information:

Retrospective review of patient outcomes after pediatric cochlear implantation and analysis of temporal bone thickness.

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)*	TBD
DEC number *(only for animal-related research)*	
Acronym/short study title	PICCOLO
Name Research Folder	xx-xxx_PICCOLO
Name Division	Heelkundige Specialismen
Name Department	Keel-, Neus-, en Oorheelkunde
Partner Organization	N/A
Start date study	01-04-2022
Planned end date study	31-07-2022
Name of datamanager consulted*	Dax Steins
Check date by datamanager	06-03-2022

1.2 Select the specifics that are applicable for your research.

- Retrospective study
- Monocenter study
- Non-WMO

The study consists of two phases. Phase 1 and 2 are both retrospective data analyses.

2. Data Collection

2.1 Give a short description of the research data.

Objective: The aim of this study is to investigate the complications and reasons for revision surgery in our pediatric CI cohort (Phase 1), and to obtain data regarding temporal bone thickness in a pediatric population in order to determine the feasibility of drilling a bony well (Phase 2).

Study Population: First phase: Clinical data from pediatric patients who underwent unilateral or bilateral cochlear implantation at the UMC Utrecht, location Wilhelmina Children’s Hospital (WKZ) from 1-1-1996 until 31-3-2021). Second phase: We will include 200 CT images (maximum one CT scan per patient) so that each age group is represented with a minimum of 100 scans (200 ears per group). The study population for phase 2 will be drawn from pediatric patients of the UMC Utrecht - location Wilhelmina Children’s Hospital (WKZ) that have undergone a CT scan which included the temporal bone bilaterally from 01-01-2021 until 31-12-2021.

Phase 1: The patient data will be extracted from the Electronic Patient Dossier (EPD)/Research data platform and reported in Excel. The data that will be assessed are: demographics, information of the surgical techniques used during operation, complications during or after surgery (if applicable) information on revision (if applicable), user or non-user at the time of last follow up.

Phase 2: The imaging data will be extracted from PACS (Picture Archiving and Communication System) by a radiologists (Radiology Department), the data will be send by the principal investigator to the UMCU's Research Imaging Architecture where the scans will be pseudonimized. The pseudonimyzed CT scans will be viewed and segmented in Mimics Materialise sotware to create 3D models. The 3D models will be exported into 3-matic Materialise software, where the analysis will take place and saved in the research folder. The results of the analysis in 3-matic will be automatically imported in an Excel document. Both Mimics and 3-matic Materialise software are ISO approved for medical research and will be used through the 3D lab of the UMC Utrecht on computers of the 3D lab. This guarantees the safety of the data.

Subjects	Phase	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	1	approximately 200-300	EPD (HiX)	Research Data Platform	Quantitative	.cvs, .sav	0-10GB
Human	2	200	Research Imaging Architecture (RIA)	Mimics Materialise	Images	DICOM	
Human	2	200	CT scans	3-matic	3D model	.stl	
Human	2	200	3D model	3-matic	Quantitative	.xlsx	

2.2 Do you reuse existing data?

- Yes, please specify

For this study, we use pseudonymized data aquired through the Research Data Platform/Research Imaging Architecture. If the data cannot be obtained thourgh the RDP, because the patient file consists of scanned information (before the use of the EPD), data will be extracted from Hix. We also use data acquired through PACS (Radiology software used in the UMC Utrecht). Data will be pseudonymized by the Research Imaging Architecture.

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

The research team is composed of:
- Dr. Hans G.X.M. Thomeer, PI
- Dr. I. Stegeman, epidemiologist
- Drs. L.M. Markodimitraki, PhD student

My division datamanager receives a datamart from the Research Data Platform (RDP) that contains direct identifying personal data (e.g. date of birth) and pseudonymized data. The datamanager is authorized to link different datasets of the selected patient group and thus has access to personal data such as patientID. The key table linking study specific IDs to patient IDs is available to the datamanager and members of the research team with a care relationship to the patient. Other members of the research team receive a pseudonymized dataset and have no access to direct personal data or the key table.

Type of data	Who has access
Direct identifying personal data	Research team with care relationship to the patient, Datamanager
Key table linking study specific IDs to Patient IDs	Research team, 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 Excel. 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.	Storage	X		
2.	Time of datamanager	X		
3	Research Imaging Architecture		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 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?	Phase	Why?
Demographics: gender, age at implantation, unilateral/bilateral (simultaneous or sequential), placement (left/right), CI model, duration of follow up, etiology of hearing loss	1	To describe our study population
Users/non-users at time of last check-up	1	To describe our study population
Surgical techniques used: type of incision, approach of cochlea, positioning and fixation technique of R/S device.	1	To describe perioperative techniques used.
Complications that occurred during and after operation. We will report when the complication took place (how long after the operation), how the complication was handled (for example by wait-and-see, antibiotics, revision surgery etc.) and if this complication lead to explantation.	1	to be able to find correlations between the surgical techniques used and the type of complication that occured and examine of there is a correlation between certain surgicl techniques and certain complications.
Revision: period of time between primary and revision surgery, causative mechanism for revision (device failure, flap-associated problems, migration, hematoma, CSF leakage, insertion problems), CI models, surgical techniques used, follow up, complications	1	to be able to find correlations between the surgical techniques used and the number of revision surgeries and examine of there is a correlation between certain surgicl techniques and the amount of revision surgeries.
CT scans	2	To assess the bone thickness of the temporal bone and the feasibility of drilling a bony well in different age groups.
(3D models)	2	(To assess the bone thickness of the temporal bone and the feasibility of drilling a bony well in different age groups.)

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

- No objection, please explain

For this study we will not acquire informed consent from the participants thereby violating article 15 (Right of access of the data subject), article 16 (Right to rectification), article 18 (Right to restriction of processing), and 21 (Right to object to use/process their personal information) of the AVG. We make use of the no objection check before processing personalized data. This study fullfils the criteria needed for the exemption rule for informed consent, according to the GDPR or AVG in Dutch.

- The processed data will be used for research and only for the purpose described in this protocol. In order to assess the complications and revisions of pediatric patients and the skull thickness in pediatric patients we need to process the study parameters as described in section 6.1. Without these parameters the results are unreliable and/or the study cannot answer the research questions. It is impossible to not use personal data descriptive statistics of our population in determining our objectives.
- The results of this study can be used to assess the complications rate in our medical center and compare the rates to other clinics. If there is a need to improve our methods this study is a necessary starting point and knowledge. Thus this would benefit children receiving a cochlear implant in future. Furthermore this study could increase the knowledge of feasibility of drilling in (young) children. This could have a significant impact on the surgical technique used and therefore could also benefit children in future.
- There are major practical problems in acquiring informed consent for this study. Some surgeries have taken place > 10 years ago. It is very likely that contact details have been changed during these years. Contacting these patients would be extremely difficult or even impossible, and the chance of successfully acquiring informed consent is very low. Due to the large sample size (we expect a cohort of >300) it would take months for the researchers to find the correct contact information. Furthermore we expect that a large percentage of the participants is not a patient in our medical center anymore, making it impossible to ask permission to inform them of this study.
- For this study we will collect and process only the necessary information for answering our research question. The privacy of the individual will therefore not be disproportionately harmed.

All in all, informed consent is not feasible for this study, and all data will be collected pseudonymized.

The objection check will be performed by the researcher before accessing the data through the RDP datamart.

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: <storage location>

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.

We will not transport any personal data outside the UMCU network drives.
Oticon Medical did not and will—by a research contract—not have influence on the data collection, analysis, data interpretation and publication. You can find the research contract in de research folder (\\ds\DATA\HS\Onderzoek\KNO\xx-xxx_PICCOLO\B_Documentation\1_METC\Funding contracts)

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.
The metadata that will be generated are:
Phase 1:

- The database in which all the variables described in our study protocol will be collected.
- The Syntax of the analysis used to interpret the data.
- The results of the analysis.
- The publication on the results of the study.

Phase 2:

- The 3D models extracted from the CT scans.
- The results of the analysis performed on the 3D models.
- The publication on the results of the study.

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. The criteria and time period will be determined on a case-by-case basis.
The publication will be openly assessable. 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.

To be determined at a later stage of this study