Plan Overview

A Data Management Plan created using DMPonline

Title: HP_CI Hearing preservation after cochlear implant surgery

Creator:Ellen Kant

Principal Investigator: H.G.X.M. Thomeer

Affiliation: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

Rationale: Although cochlear implantation was conventionally a preserved treatment for complete bilateral hearing loss, more patients with residual hearing receive a cochlear implant nowadays due to widened indication criteria including medical indications like tinnitus (Sprinzl et al. 2020, Gstoettner et al. 2004). Therefore, hearing preservation has become more important, with the potential to improve speech discrimination and preserve the possibility to benefit from future discoveries (Skarzynski et al. 2013, Sierra et al. 2019). There is merit in attempting to preserve residual hearing and various factors may influence this such as the use of an atraumatic electrode and additional measures as corticosteroids (Sprinzl et al. 2020, Skarzynski 2018, Dhanasingh et al. 2017, Adunka et al. 2006, Gstoettner et al. 2003). Consequently, the aim of this study is to determine the hearing preservation after cochlear implantation surgery in patients with residual hearing. Additionally, we aim to determine the correlation between the hearing preservation and peri-operative factors and patient characteristics. Lastly, we determine whether there is a correlation between the hearing preservation and the speech audiometry outcomes months to years after cochlear implantation. Objective: The primary aim of this study is to determine the hearing preservation after cochlear implantation surgery in patients with residual hearing. The secondary aim of this study is to determine the association between the hearing preservation and the used electrode array, use of corticosteroids perioperatively, speech perception outcomes, the use of electric acoustic stimulation, patient characteristics and side of implantation Study design: The proposed study is a retrospective cohort study. Study population: Clinical data from adult patients (18 years and older) who underwent unilateral or bilateral cochlear implantation at the UMC Utrecht from 01-01-2015 until 23-10-2020. Main study parameters/endpoints: To determine the primary objective, the main study endpoint is the mean hearing preservation according to the Hearing Preservation Classification System (Skarzynski et al. 2013). This will be based on Pure Tone Audiometry outcomes pre-operative and post-operative of the frequencies 125Hz, 250Hz, 500Hz. The secondary endpoints of this study will be, the correlation between hearing preservation and electrode array, CI model, use of corticosteroid perioperatively, patient characteristics: age, gender and side of implantation and speech perception outcomes approximately six and twelve months post-operatively. Additionally, the following data will be extracted for describing the population: the medical indication (i.e. diagnosis) for cochlear implant surgery and the use of electric acoustic stimulation. Nature and extent of the burden associated with participation, benefit and group relatedness: Since the proposed study regards a retrospective cohort study, there is no burden with participation. Possible benefits for future CI patients would be better preoperative counselling regarding hearing preservation.

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HP_CI Hearing preservation after cochlear implant surgery

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)	Volgt
DEC number (only for animal-related research)	
Acronym/short study title	XX-XXX_HP_CI
Name Research Folder	Volgt
Name Division	Surgical specialties
Name Department	Otolaryngology
Partner Organization	
Start date study	
Planned end date study	
Name of datamanager consulted*	Dax Steins
Check date by datamanager	21-12-2020

1.2 Select the specifics that are applicable for your research.

- Monocenter study
- Retrospective study
- Non-WMO
- Observational study

2. Data Collection

2.1 Give a short description of the research data.

Objective: With this study, we want to investigate hearing preservation after cochlear implantation by retrospectively analyzing PTA outcomes pre- and postoperative

Population: Patients who underwent unilateral or bilateral cochlear implantation at the UMC Utrecht in years 2015-2020 (1-1-2015 until 23-10-2020)

Main study parameter: Pure Tone Audiometry outcomes

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	150	EPD (RDP/HiX)	Excel	Quantitative	.xlx	0-10GB

2.2 Do you reuse existing data?

- Yes, please specify

In this retrospective study, we use pseudonymized data made available for research by Research Data Platform(RDP).

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

Type of data	Who has access
Personal data	PI, datamanager, Research team with care relationship to the patient
Key table linking study specific IDs to Patient IDs	PI, datamanager, research team relationship with care of patients identifying personal data
Pseudonymized data	Research team

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

#	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.				
4.				
5.				

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. To answer this, I consulted the division datamanager.

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

Which personal data?	Why?
Gender, age at implantation, indication for surgery	To describe our study population, to be able to find correlations
Operative report	To describe perioperative measures
Pure tone audiometry and speech audiometry	To describe the hearing levels pre and post operative

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

- No objection, please explain

We make use of the no objection check before we process any personalized data. We make use of the exemption rule for informed consent, according to the GDPR
or AVG in Dutch, and we fulfill the 4 criteria needed for this exemption rule.

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>
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.

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.

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

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.

We use metadata standards for the codebook and excel analysis. Additionally, the descriptive metadata of the Pure Tone Audiometry and Speechaudiometry outcomes will also be collected.

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

6. Data Analysis

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

I have written an analysis plan in which I state why I will use which data and which statistical analysis we plan to do in which software. The analysis plan is stored in the project folder, so it is findable for my peers.

7. Data Preservation and Archiving

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

The raw data, i.e. PTA scores will be included in the data package. The data in excel file describing the PTA scores and perioperative measures will also be added. In addition, the following files are added: the study protocol describing the methods and materials, a codebook with explanations on the variable names used in the excel files for capturing the data, 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.

My peers will be reusing all research data in the final dataset to generate new research questions.

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)

To be determined

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

To be determined

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

To be determined

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

To be determined