Hearing preservation after cochlear implant surgery

A Data Management Plan created using DMPonline

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Funder: University Medical Center 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.

Last modified: 03-02-2021

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1. General features

<table>
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<th>DMP template version</th>
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<tr>
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<td>Volgt</td>
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<tr>
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<td>DEC number (only for animal-related research)</td>
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<td>Planned end date study</td>
<td></td>
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<tr>
<td>Name of datamanager consulted*</td>
<td>Dax Steins</td>
</tr>
<tr>
<td>Check date by datamanager</td>
<td>21-12-2020</td>
</tr>
</tbody>
</table>

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

2. Data Collection

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

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Volume</th>
<th>Data Source</th>
<th>Data Capture Tool</th>
<th>File Type</th>
<th>Format</th>
<th>Storage space</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human</td>
<td>150</td>
<td>EPD (RDP/HiX)</td>
<td>Excel</td>
<td>Quantitative</td>
<td>.xlx</td>
<td>0-10GB</td>
</tr>
</tbody>
</table>

- Yes, please specify

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

<table>
<thead>
<tr>
<th>Type of data</th>
<th>Who has access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal data</td>
<td>PI, datamanager, Research team with care relationship to the patient</td>
</tr>
<tr>
<td>Key table linking study specific IDs to Patient IDs</td>
<td>PI, datamanager, research team relationship with care of patients identifying personal data</td>
</tr>
<tr>
<td>Pseudonymized data</td>
<td>Research team</td>
</tr>
</tbody>
</table>
1. Do you use a certified Data Capture Tool or Electronic Lab Notebook?  
   - Yes

2. Have you built in skips and validation checks?  
   - Yes

3. Do you perform repeated measurements?  
   - Yes

4. Are your devices calibrated?  
   - No

5. Are your data (partially) checked by others (4 eyes principle)?  
   - No

6. Are your data fully up to date?  
   - Yes

7. Do you keep a logging (audit trail) of all changes?  
   - Yes

8. Do you have a policy for handling missing data?  
   - Yes

9. Do you have a policy for handling outliers?  
   - Yes

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)

   - 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.

<table>
<thead>
<tr>
<th>Which personal data?</th>
<th>Why?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, age at implantation, indication for surgery</td>
<td>To describe the study population, to be able to find correlations</td>
</tr>
<tr>
<td>Operative report</td>
<td>To describe perioperative measures</td>
</tr>
<tr>
<td>Pure tone audiometry and speech audiometry</td>
<td>To describe the hearing levels pre and post operative</td>
</tr>
</tbody>
</table>

   - 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.

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.
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.

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

4. Data Storage and Backup

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.

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

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.

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

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

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.

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

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.

There are no plans to publish the full dataset, however we consider publishing 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

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

- Yes (please specify)
To be determined

To be determined

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

To be determined