Plan Overview

A Data Management Plan created using DMPonline

Title: Cholesteatoma disease recurrence after the endoscopic approach or canal wall up tympanomastoidectomy with versus without bony obliteration

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Template: UMC Utrecht DMP

Project abstract:

The primary aim of this study is to investigate whether canal wall up tympanomastoidectomy with bony obliteration of the mastoid reduces cholesteatoma recurrent and residual rates compared to the same approach without bony obliteration. Secondly, hearing outcomes after both surgical techniques are compared to investigate whether one of the two mentioned techniques result in better postoperative hearing. The same two aims will be investigated when comparing the canal wall up tympanomastoidectomy (microscopic technique) with the endoscopic technique to remove cholesteatoma.

It is a retrospective cohort study.

Study population: Clinical data from patients who underwent a canal wall up tympanomastoidectomy, with or without bony obliteration, for cholesteatoma between January 1, 2015 and December 31, 2020 in the UMC Utrecht will be obtained from HiX (electronic health record system).

Main study parameters/endpoints: Rates of recurrent or residual cholesteatoma are evaluated mainly by MRI Diffusion Weighted Imaging (MRI DWI) approximately 12 months after surgery. If diffusion restriction is seen, recurrent or residual disease is suspected and will be recorded. To determine whether the cholesteatoma is either recurrent or residual, we will analyse the tympanic membrane description at the beginning of the revision surgery: a retracted tympanic membrane with cholesteatoma correlates with recurrent disease (clinical diagnosis), whereas cholesteatoma formation behind a normal or an intact tympanic membrane correlates with residual disease (radiographic diagnosis). Pure tone audiograms, including air and bone conduction, and speech recognition scores are evaluated pre- and postoperatively in each patient to compare the hearing outcomes for both surgical techniques.

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Copyright information:

Cholesteatoma disease recurrence after the endoscopic approach or canal wall up tympanomastoidectomy with versus without bony obliteration

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)*	MvdL/mb/21/500229
DEC number *(only for animal-related research)*	
Acronym/short study title	CATBOT
Name Research Folder	xx-xxx_CATBOT
Name Division	Divisie Heelkundige Specialismen
Name Department	KNO
Partner Organization	N/A
Start date study	
Planned end date study	
Name of datamanager consulted*	Dax Steins (versie 1) / Nivard Koning (versie 2)
Check date by datamanager	15-02-2024

1.2 Select the specifics that are applicable for your research.

- Retrospective study
- Non-WMO
- Monocenter study

2. Data Collection

2.1 Give a short description of the research data.

Objective: to investigate whether a canal wall up approach with subsequent bony obliteration reduces recurrent and residual disease rates for cholesteatoma when compared to canal wall up approach without bony obliteration. The same objective will be investigated when comparing the canal wall up approach (microscopic approach) with the endoscopic approach.

Population: clinical data from adult patients who underwent an endoscopic approach or canal wall up approach with or without bony obliteration in the period between January 1, 2015 and December 31, 2020, in the UMC Utrecht. Follow-up is completed until latest December 31, 2023 to allow three year follow-up for all included patients.

Main study parameter: recurrent or residual disease after approximately one and three years follow-up.

Dataflow: clinical data (patient demographics, medical history, surgery reports and audiograms) will be obtained manually from HiX and recorded in Excel. From PACS MRI images will be obtained when necessary. We do not expect to use PACS often, because the conclusions of the MRI images can be obtained from HiX. However, when the outcome is inconclusive, it might happen that we have to look at the images in PACS.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	150-200	EPD (HiX)	Excel	Quantitative	.xlsx	0-10 GB
Human	150-200	PACS	Excel	Quantitative	.xlsx	0-10 GB

2.2 Do you reuse existing data?

- Yes, please specify

In this retrospective study we do not use the RDP, because of the type of data needed such as data from surgery reports. The clinical data will be manually extracted from HiX under direct supervision of the surgeon with a care relationship with the patients. After this, the data will be coded and only the surgeon with a care relationship with the patients will have access to the key file with patient numbers.

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

Type of data	**Who has access**
Direct identifying personal data	PI (with a care relationship to the patient), DHS Datamanager.
Key table linking study specific IDs to Patient IDs	PI (with a care relationship to the patient), DHS Datamanager.
Coded data	Research team (without care relationship with patient), DHS Datamanager.

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.	Time of datamanager	X		
2.	Storage	X		
3.	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 cholesteatoma patient group. It may be used to find study subjects for future research. 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). The department of Otorhinolaryngology will take care of the data for a minimum of 15 years.

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 have consulted the DHS data manager 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?
Patient demographics	To describe our study population.
CT images	To describe our study population (whether they have or do not have destruction of bony structures)
MRI-images	To answer the research question (whether they have or do not have recurrent disease)
Operative report	To describe our study population (the type of surgery, extent of cholesteatoma during surgery, and possible complications)

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 processing personal data. The researcher receives the dataset on the same date as when the objection check is performed on the RDP datamart, dd-mm-yyyy)

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

We make use of the no objection check before we process any personalized data. We will use the informed consent exemption rule according to the GDPR (AVG) and we will fulfil the criteria needed for this exemption rule. This study is in public interest of patients with a cholesteatoma as this study might prove a statistically and clinically significant decrease in recurrent rates after the bony obliteration technique compared to the non-bony obliteration technique. This would reduce the number of operations, which is both good for the patient as well as society as a whole. Currently, there is still no agreement on the best surgical approach and evidence on this specific technique in combination with the canal wall up approach is limited.

To conduct this research personalized data is necessary to obtain postoperative MRI scans and audiograms to gain insight in recurrent disease and hearing outcome, respectively.

An opt-in approach, actively acquiring informed consent requires unreasonable effort for the researchers as most of the treated patients have undergone surgery many years ago. Since active follow-up ended for most patients and they do not return on a regular basis to the UMC Utrecht or receive care in a different (most likely peripheral) hospital, it is highly likely that their contact details will have changed. Reaching these patients, if possible at all, would be extremely time consuming. Furthermore this would lead to a high non-response rate. In conclusion there are major practical problems in acquiring informed consent for this study. Therefore, informed consent is not feasible for this study, resulting in a violation of article 15, 16 and 18 GDPR, considering the right to restriction of processing.

The other rights are not applicable.

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 +/- 50 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.

I prepared a codebook of my research database. In SPSS I will save the metadata from all analysis and processes.

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.

We will be using SPSSS, version 29.0.1, for statistical analysis of the data. The scripts will contain comments, such that every step in the analysis is documented and peers can read why I made certain decisions during the analysis phase.

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, an overview of the analysis of 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 from this non-WMO study will be saved for at least 15 years. After finishing the project, all documents and data will be stored at the UMC Utrecht.

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. The data package will be published in DataverseNL.

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

I will be using a DOI-code and will update this plan as soon as I have the code.

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 in the ENT-field or for other follow up projects. Internal colleagues within the ENT department can reuse our data. We do not know yet which data we will make public available.

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. If data is shared, this will only be anonymous data, in order to protect patient privacy.

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

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

After completion of the project and after publication of the last planned article using this data, we will publish the Metadata in DataverseNL for reuse.

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

The metadata will be published on DataverseNL after the research is finished.