Plan Overview

A Data Management Plan created using DMPonline

Title: Metaplasia of the hip capsule after Shelf arthroplasty or Chiari osteotomy

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Template: UMC Utrecht DMP

Project abstract:

Hip dysplasia is a mal development disease of the hip joint. The most frequent presentation of hip dysplasia is a shallow acetabulum with insufficient superior coverage of the femoral head.1 Patients with symptomatic dysplasia of the hip can suffer from groin pain, abnormal gait, decreased strength, and increased rate of degenerative hip disease.1,2 Treatment in adults are all surgical. Shelf arthroplasty and Chiari osteotomy are techniques that intend to increase the acetabular weight bearing surface.3,4 Next to the mechanical action, the success of these surgical techniques might rely on metaplastic deformation of the hip capsule to fibrocartilage. This hypothesis has been described by prof. K. Chiari in 1976.4 However, it has only be researched in animals and small populations.

The aim of this study is to perform a histological analysis of the capsule after Shelf arthroplasty or Chiari osteotomy. Staining will be done to discern if there is metaplasia of the capsule to fibrocartilage tissue. The study population includes patients that are 18 years and older, with a medical history of Shelf arthroplasty or Chiari osteotomy, that have an total hip arthroplasty (THA) indication because of secondary arthritis of the hip. The patients will receive care as usual for a THA. The tissue that will be used for analysis is removed in every THA and can be seen as “waste material”.

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Metaplasia of the hip capsule after Shelf arthroplasty or Chiari osteotomy

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)*	
METC number *(only for human-related research)*	
DEC number *(only for animal-related research)*	
Acronym/short study title	MaSC
Name Research Folder	xx-xxx_MaSC
Name Division	Heelkundige specialismen
Name Department	Orthopedie
Partner Organization	St Maartens Kliniek Nijmegen, OLVG Amsterdam, OCON Hengelo, Diakonessenhuis Utrecht/Zeist
Start date study	01-09-2022
Planned end date study	01-03-2024
Name of datamanager consulted*	Nivard Koning
Check date by datamanager	9-9-2022

1.2 Select the specifics that are applicable for your research.

- Prospective study
- Non-WMO
- Biobank approval needed: "uitgifteprotocol"
- Observational study
- Multicenter study

Design: cross-sectional analysis at the time of secondary osteoarthritis
Setting: histologic analysis of interposed hip capsule (waste material after total hip arthroplasty)

2. Data Collection

2.1 Give a short description of the research data.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	5-10	eCRF	castor	Quantitative	.cvs	<1GB

A histological analysis of the metaplastic changes of the interposed hip capsule after shelf arthroplasty or Chiari osteomy. The Data wil include descriptions of the tissue's characteristics and a comparison to fibrocartilage in term of chondroid matrix and collagen fibres. Next to this the age, gender and medical history will be collected.

2.2 Do you reuse existing data?

- Yes, please specify

In this prospective study we newly collect specimens to perform a histologic analysis. Data about the age, gender and medical history of these patients will be collected from existing patient files (EPD) e.g. Hix or Epic.

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

Type of data	Who has access
Pseudomized patient data (age, gender, medical history*)	N. Koning (data manager) B.C.H. van der Wal (Principal investigator) M.F.T. Hüsken (Coordinating researcher) P. Nikkels (pathologist)
Description of Histology analysis	N. Koning (data manager) B.C.H. van der Wal (Principal investigator) M.F.T. Hüsken (Coordinating researcher) P. Nikkels (pathologist)
Identifying Data	treating surgeon from participating hospital, (not involved in research team)

The specimen will be collected without personnel data and therefore be numbered by hospital. The code will only be available in the treating hospital, to the orthopaedic surgeon treating the participant, and not available for the research team.

* Medical history contains: Previous hip surgeries and diseases possibly affecting bone or cartillage formation.

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

Data/measurements derived from the histological analysis and patient data will be kept in Castor. Important measurements will always be done twice and checked by others. Data will be kept in different versions with the addition of the date after the filename, as mentioned above, therefore the last version will be fully up-to date and the last additions or lost data can easily be retrieved.

#	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*

* The data will be analysed with colourings and and reported discriptively. Missing data and outliers will be descibed but cannot be handled.

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 data manager	x		
2.	Storage	x		
3.	Data Capture Tool license fee (Castor)	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.

The patient will stay owner or their own tissue/material, with the rarties solely acting as a custodian of the Material. The UMC Utrecht is and remains the owner of all data collected from the performed analysis. Our data cannot be protected with IPR, but its value will be taken into account when making our data available to others. The This is contractually agreed upon in a Material and associated Data Transfer Agreement.

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

The original specimen are tranfered and stored pseudomized without personal data. The name, date of birth or any other high risk specifics from these patients will not be available to the researchers. We do collect age, gender, medical history and specimen with DNA and therefore indirect identifying data.

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

Which personal data?	Why?
Gender, age	To describe our study population
Relevant medical history (previous hip surgeries and diseases possibly affecting bone or cartillage formation)	To avoid bias
Specimen from the hip capsule, this includes genetic data and therefore personal data.	The research can not be performed without the data.

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

- Study-specific informed consent

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

1. The data are pseudonymized and the linking table to personal data is saved and not available for the research team. The treating orthopedic surgeon manages the linking table for its own patients, can re-identify study participants when necessary and deliver, correct or delete the data.

Right	Example answers
Right of Access	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.
Right of Rectification	The authorized person will give the code for which data have to be rectified.
Right of Objection	We use informed consents.
Right to be Forgotten	In the informed consent we state that the study participant can stop taking part in the research. Removal of collected data from the research database cannot be granted because this would result in a research bias.

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 have a Data and Material Transfer Agreement with all participating centers. The agreement is stored digital in the secured research folder. Direct identifying data will not be shared. Data on age, gender and medical history will be shared through Castor. Specimen will be tranfered in formallin by a secure courier or collected by a member of the research team and brought to the pathology department.

4. Data Storage and Backup

4.1 Describe where you will store your data and documentation during the research.

UMC Utrecht is initiator of this multicenter study. The specimen are stored at the pathology lab before analysis and will be destroyed afterwards. The derived data will be stored on the standard IT-system of the UMC Utrecht, in the secured Research Folder Structure with restricted access for the research team only. The data will not be accessible outside of the Hospital network. Direct indentifying data like the keytable and pseudoID will stay at the treating hospital and will not be shared with the UMC Utrecht. All versions of the databases will be saved before editing with the addition of the current date to directly backup previous versions.

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). For analysis, all versions of the databases will be saved before editing with the addition of the current date to directly backup previous versions.

5. Metadata and Documentation

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

For the data collected in Castor, a codebook of my research database is available in Castor.
Metadata that will be generated are the following:
- Staining techniques used for histology 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 date with initials after each edit, for example 02-02-2022, MH. 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 date in the filename. The most recent version is kept and older versions are moved to a folder OLD.

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 staining techniques an how we plan to analyse the specimen. The analysis plan is stored in the project folder, shared with participating hospitals and included in the publication, 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 data package will contain: Pictures of the stained specimen, the study protocol describing the methods and materials, 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. The data package with descriptons will be published in the UMC Utrecht repository (Dataverse NL)

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

The publication will be open accessible. The study protocol and anonymized data, needed to reproduce findings will also be available. A DOI will be assigned to all publications.

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. Our processed genetic data can be of interest for other Europeans researchers in the field.

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?

- No, all data generated in this project will be made publicly available without any restrictions

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

The publication will be open accessable. The study protocol and this Data Management Plan will also be available.

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 data package with descriptions will be published in the UMC Utrecht repository (DataverseNL). Dataverse is open source

software developed by Harvard University. Results and meta data will be published in an article.