Mid term outcomes of arthoscopic scapholunate dorsal capsuloplasty: a prospective cohort study.

A Data Management Plan created using DMPonline

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Template: UMC Utrecht DMP

Project abstract:

Rationale: The Mathoulin repair is a minimal invasive procedure. With the use of a wrist arthroscope a dorsal capsuloplasty is performed. Since its introduction in 2011, only two short-term reports have been published. Moreover, not much is known about longer-term outcomes of this procedure in terms of pain and disability in daily life. Objective: to investigate patient-reported outcomes after the arthroscopic dorsal capsuloplasty in patients with scapholunate ligament injury. Study design: this is a monocenter prospective study intervention without control group. Study population: patients who underwent the arthroscopic dorsal capsuloplasty procedure between 01-01-2014 and 31-06-2020 at the University Medical Centre Utrecht, the Netherlands. Intervention: arthroscopic dorsal capsuloplasty Main study parameters/endpoints: the outcomes of the quickDASH questionnaire, the PRWHE questionnaire, and VAS pain scores.

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Copyright information:

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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	ARTHROSL
Name Research Folder	xx-xxx_ARTHROSL
Name Division	Heelkunde
Name Department	Plastische chirurgie
Partner Organization	
Start date study	01-07-2021
Planned end date study	01-09-2021
Name of datamanager consulted*	DHS-datamanagement@umcutrecht.nl
Check date by datamanager	16-06-2021

1.2 Select the specifics that are applicable for your research.

- Prospective study
- Monocenter study
- Clinical study
- Use of Questionnaires
- Non-WMO

2. Data Collection

2.1 Give a short description of the research data.

Objective: to investigate the effectiveness of arthroscopic dorsal capsuloligamentous repair in patients who have scapholunate ligament injury. We will study this effect by measuring patient-reported outcomes in terms of hand function, disability and pain after a minimum follow-up duration of one year. The main study parameter is hand function measured with the PRWHE questionnaire. The secondary parameters are disability measures with the QuickDash and pain measured with VAS questionnaire

Population: all patients who underwent an arthroscopic scapholunate ligament repair between 01-01-2014 and 31-06-2020 at the UMC Utrecht, the Netherlands.

After given informed consent, the patient will receive a unique identifier, after which members of the research team will extract all necessary clinical parameters from the electronic health records (EHRs, HiX) into an electronic Case Report Form (eCRF) the UMCU endorsed system Castor EDC. Castor EDC is a browser-based, metadata-driven EDC software solution and workflow methodology for building and managing online databases. The clinical database will be supplemented with the outcome of the uppermentioned questionnaires, which will be automatically sent via an email url-link via Castor (ePRO) at set times.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	17	eCRF	Castor	Quantitative	.csv / .xlsx / .sav	0-10 GB
Human	17	ePRO	Castor	Survey	.csv / .xlsx / .sav	0-10 GB

2.2 Do you reuse existing data?

- Yes, please specify

In this prospective study, we will generate new PROM follow-up data and reuse data from our electronic health records to determine baseline characteristics.

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

Type of data	Who has access
Direct identifying personal data	Research team, 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.

Experimental data from patients will be collected in an electronic Case Report Form (eCRF) in a certified Data Capture Tool: Castor. In the eCRF, skips and validation checks are built in. Data quality will be checked by the researchers. Data collection will be frozen before analysis.

#	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.

Not applicable.

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.

1. UMC Utrecht is and remains the owner of all collected data for this study. The data is collected in a relatively small 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

2. I will process personal data. I have consulted the division datamanager 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?**
Name and email address of participants	To be able to invite participants for taking part in the research and to send them questionnaires
Patient demographics (Gender, Age, etc...)	To describe our study population
Baseline measurements (Operated hand, dominant hand, etc..)	To report baseline characteristics in order to have insight which type of patients are operated
3 questionnaires: PRWHE, Quickdash, VAS pain	To report patient reported outcomes

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.

Right	**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.

1. 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.
2. We make use of a certified Electronic Data Capture (EDC) tool (Castor). To send surveys, email address will be used in the EDC, but this is encrypted for the users in such a way that users can send emails to subjects without seeing the actual email address. No personal data other than email address will be used in the EDC.

3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.

1. 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 +/- 1 GB storage space, so the capacity of the network drive will be sufficient. Since this is a relative small research, we do not expect to exceed 1GB of storage space.

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.

1. All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).
2. During data collection, automatic backups will be made in the Electronic Data Capture Tool Castor. 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.

1. Castor automatically makes a data dictionary of the data collected.

5.2 Describe your version control and file naming standards.

1. 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.

1. I will make an overview of datasets and analysis scripts, such that it is fully clear how the statistical analysis is performed. 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.

1. 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.

1. 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.

1. 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.

1. 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.

1. The research data of the final dataset can be of interest for other researchers studying arthtroscopic SL repair or for spin off projects.

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)

As the data is privacy-sensitive, we publish the descriptive metadata in the data repository with a description of how a data request can be made (by sending an email to

the corresponding author). 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 informed consent signed by the study participants. Every application therefore will be screened upon this requirement. If granted, a data usage agreement is signed by the receiving party.

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

1. All data and documents in the data package mentioned in 7.1 will be shared under restrictions.

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.

1. I will provide a link to the data repository or a link to the dataset upon request.