Evaluation of ultrasound in patients with primary and secondary cubital tunnel syndrome

A Data Management Plan created using DMPonline

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Template: UMC Utrecht DMP

Project abstract:

For the diagnosis of cubital tunnel syndrome (CuTS), the 2011 CBO-guideline (Centraal Begeleidings Orgaan) recommends considering measurement of thickening of the ulnar nerve using ultrasound in addition to the electromyography. This can be done in several different ways, for example using direct measurement, the cross-sectional area (CSA), or the swelling ratio of the ulnar nerve. Many studies found the CSA and swelling ratio of the ulnar nerve to have good diagnostic accuracy when it comes to nerve entrapment. However, studies on diagnostic value of ultrasonography are mainly performed in preoperative patients with (possible) ulnar neuropathy. Though barely studied, another interesting group is the one with persisting or recurrent symptoms after decompression. Only two small studies (n=10 and n=8) looked at the diagnostic value of ultrasonography in this patient group and found ultrasonography to be useful in terms of qualifying the need for surgical treatment. We will evaluate CSA measurements in both primary and secondary neuropathy patients in a tertiary centre. Objective: To evaluate the diagnostic role of CSA measurements using ultrasound in patients with both primary and secondary cubital tunnel syndrome. Study design: Retrospective consecutive case series. Study population: Adult patients with CuTS between 01-01-2015 and 01-01-2021. Main study parameters/endpoints: The main study parameter is the CSA (Cross-Sectional Area) of the ulnar nerve at the cubital tunnel measured using ultrasound.

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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)*	21-143
DEC number *(only for animal-related research)*	
Acronym/short study title	CuTS
Name Research Folder	21-143_CuTS
Name Division	Heelkundige Specialismen
Name Department	Plastische Chirurgie
Partner Organization	N/A
Start date study	01-01-2021
Planned end date study	01-04-2021
Name of datamanager consulted*	Dax Steins
Check date by datamanager	25-01-2021

1.2 Select the specifics that are applicable for your research.

- Non-WMO
- Retrospective study
- Monocenter study

2. Data Collection

2.1 Give a short description of the research data.

Objective: To evaluate the diagnostic role of cross-sectional area (CSA) measurements using ultrasound in patients with both primary and secondary cubital tunnel syndrome (CuTS).

Study design: Retrospective consecutive case series.

Study population: Adult patients diagnosed with CuTS who visited the Plastic Surgery Outpatient Department at UMC Utrecht between 01-01-2015 and 01-01-2021.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	30	EPD (HiX)	Research Data Platform	Quantitative	.xlsx	0-5 GB
Human	30	EPD (HiX)	Excel	Quantitative	.xlsx	0-5 GB

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). Additional data, which cannot be collected via the RDP will be manually collected from HiX.

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

My division datamanager receives a datamart from the Research Data Platform (RDP) that contains direct identifying personal data (e.g. date of birth) and pseudonymized data. The datamanager is authorized to link different datasets of the selected patient group and thus has access to personal data such as patientID. The key table linking study specific IDs to patient IDs is available to the datamanager and members of the research team with a care relationship to the patient. Other members of the research team receive a pseudonymized dataset and have no access to direct personal data or the key table.

Type of data	Who has access
Direct identifying personal data	Research team with care relationship to patient, Datamanager
Key table linking study specific IDs to Patient IDs	Research team with care relationship to patient, appointed researcher by the PI (N. Boers), Datamanager
Pseudonymized data	Research team, Datamanager

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

All data (patient characteristics, disease characteristics and treatment data) will be checked by a researcher authorized by the clinician and 20% will be checked by a second a researcher authorized by the clinician. 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.

#	Type of costs	Division ("overhead")	Funder	Other (specify)
1.	Time of datamanager	X		Datamanagement by N. Boers (free)
2.	Storage	X		
3.	Archiving			X, See below

1. Besides the data fromt the division datamanager, further data will be collected by N. Boers.

3. Where data will be archived and how these costs will be covered has yet to be determined. This answer will be updated later

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 very specific patient group (also including CuTS patients with previous surgery, which is not done previously) and is very valuable for further, broader studies in Europe. 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.

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

Which personal data?	**Why?**
Baseline characteristics (e.g. gender, age at surgery, age at diagnosis, surgery type, surgery side)	To describe the study population, to reproduce the research and to support hypothesis
Diagnostic outcomes (i.e. symptoms, ultrasound outcomes including CSA measurements and anatomical variatons, EMG outcome)	To support hypothesis

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

- Study-specific informed consent

All patients with a CuTS diagnosis and CSA measurements (based on feasability research, in accordance with the 'AVG wetgeving'), will be asked to give informed consent on use of patient data in our study.

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

The PI has a care relationship to the patients. We use informed consents. 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.
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. 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 +/- 50 GB storage space, so the capacity of the network drive will be sufficient. 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.

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.

The datadictionary and overall research project will be available in the Research Folder for all involved researchers.

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. 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.

Research data will be collected in an Excel spreadsheet and imported for statistiscal analysis in

SPSS Statistics 24. The statistical analysis procedure
can be found in detail in our research proposal.
The analysis plan is stored in the project folder, so it is findable for my peers at UMC Utrecht.
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.

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 and a codebook with explanations on the variable names.

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.

To be determined

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

To be determined

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.

To be determined.

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

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 as soon as article is published

To be determined.

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

To be determined.