Plan Overview

A Data Management Plan created using DMPonline

Title: Functioning and quality of life after free muscle flap coverage as last resort for therapy-resistant neuropathic pain in the upper extremity: a long-term retrospective follow-up study

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Funder: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

Rationale: Neuropathic pain, as the result of peripheral nerve injury or chronic compression of a peripheral nerve, is accompanied by a major impact on physical functioning and quality of life. If patients fail to improve after decompression, transposition, or extensive neurolysis with coverage of local flaps, an extensive neurolysis with a subsequent free muscle flap can be performed. The goal is to create a scar-free, traction-free, well padded, and well-vascularized environment for the nerve. Using free muscle flaps for this indication is rare and outcomes of this procedure are scarcely reported.

Objective: To evaluate functional outcomes after extensive neurolysis with a subsequent free muscle flap at long-term follow-up.

Study design: This is a retrospective and prospective cohort study.

Study population: All consecutive patients who received an extensive microsugical neurolysis with subsequent free gracilis muscle flap coverage for persistent neuropathic pain in the upper extremity between January 1st 2015 and December 31st 2021 in University Medical Center Utrecht.

Main study parameters/endpoints: The main study parameters include PROMs, using six validated questionnaires:

- Quality of life, using the EQ-5D-5L
- Quick version of the Disabilities of the arm, shoulder, and head questionnaire (Quick-DASH)
- Hand function, using the Michigan hand outcomes questionnaire (MHQ)
- Neuropathic pain components, using the PainDETECT Questionnaire (PD-Q)
- General health, using the SF-36
- Pain, using VAS scores

Nature and extent of the burden associated with participation, benefit and group relatedness: The burden is negligible since patients are asked to fill in a few questionnaires (duration approximately 15 minutes). Details on disease characteristics and treatment characteristics will be collected retrospectively. There will be no additional measurements and/or diagnostics. Diagnosis and treatment will remain the same, regardless of participation. Patients will not benefit from participating in this study. However, patients will add to the current knowledge to further improve the optimal treatment regime in patients with neuropathic pain.

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Copyright information:

Functioning and quality of life after free muscle flap coverage as last resort for therapy-resistant neuropathic pain in the upper extremity: a long-term retrospective follow-up study

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)*	TBD
DEC number *(only for animal-related research)*	
Acronym/short study title	Long-term follow-up after free muscle flap coverage for therapy-resistant neuropathy
Name Research Folder	xx-xxx_GRACILIS
Name Division	Heelkundige Specialismen
Name Department	Plastische Chirurgie
Partner Organization	N/A
Start date study	15-10-2022
Planned end date study	15-10-2023
Name of datamanager consulted*	Nivard Koning
Check date by datamanager	26-8-2022

1.2 Select the specifics that are applicable for your research.

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

This is a retrospective and prospective study, using data retrieved from HIX and one-time questionnaires. There will be no additional measurements and/or visits in this study.
Primary Objective:

- To evaluate the long-term outcomes of a free muscle flap coverage as a final treatment option for persistent neuropathic pain in the upper extremity.

The main study parameters include PROMs, using six validated questionnaires:

- Quality of life, using the EQ-5D-5L
- Quick version of the Quick-DASH
- Hand function, using the MHQ
- Neuropathic pain components, using the PD-Q
- General health, using the SF-36
- Pain using VAS scores.

Secondary Objective(s):

- To compare outcomes of the reconstruction

The secondary study parameters include data retrieved from HiX:

- Occurrence of complications during and after surgery.
- Symptoms before and after surgery.

All questionnaire licences have been obtained.

2. Data Collection

2.1 Give a short description of the research data.

See 1.2 for primary and secondary objectives and parameters from questionnaires and HiX.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	20-40	EQ-5D-5L	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	20-40	Quick-DASH	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	20-40	MHOQ-DLV	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	20-40	SF-36	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	20-40	PD-Q	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	20-40	VAS-score	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	20-40	HiX	Castor	Quantitative	.sav	0-10 GB

2.2 Do you reuse existing data?

- No, please specify
- Yes, please specify

Yes, for the retrospective part of this study, details on complications, patients characteristics, symptoms and surgery characteristics will be collected from HiX.

No, for the prospective part of this study, data on general health, quality of life, functionality and pain will be collected through one-time questionnaires.

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

Type of data	Who has access
Pseudonymized data	Principal Investigator, research team, datamanager
Key table linking study specific IDs to Patient IDs	PI (with care relationship to patient, supervising), Research team, Datamanager
Direct identifying personal data	PI (with care relationship to patient, supervising), Research team, Datamanager

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

Filled out questionnaires from patients will be collected in an electronic Case Report Form (eCRF) in a certified Data Capture Tool: Castor (ePRO). Data collection will be frozen before analysis. Data will be matched by study subject code. We use in total 6 questionnaires. At the end of the study data will be extracted from Castor to SPSS.

Data will be collected after informed consent of participants is received, by N. Boers and E. List. Completeness will be checked and if not complete patients will be send a reminder to complete the questionnaires. If data is missing in the end than this will not be used for the statistical 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			Datamanagement by E.B. List (free)
2.	Design of eCRF			By E.B. List (free)
3.	Data capture Tool license fee			Free
4.	Questionnaire license fee			Free
5.	Storage			See below

5. 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 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)

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?
Name and email address of participants	To be able to invite participants for taking part in the research and to send them questionnaires
Patient characteristics, symptoms, surgery characteristics	To describe our study population and answer the research question
General health	To answer our research question
Quality of life	To answer our research question
Disabilities of hand/arm	To answer our research question
Hand function	To answer our research question
Neuropathic pain components	To answer our research question
Pain score	To answer our research question

See the research protocol for further specifications of the personal 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. An authorized person manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data.

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 authorised person (PI or datamanager). The request for this must be submitted in writing to the PI.
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.

1. The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht. For analysis, data will be extracted to excel and analysed in SPSS. 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. For the data collected in Castor, a codebook of my research database is available in Castor.
2. After data analysis, a SPSS codebook is available.

5.2 Describe your version control and file naming standards.

1. We will keep track of changes using descriptions of changes per datestamp for each file in a separate Word document.
2. 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 and older versions are moved 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 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 described in the nWMO protocol of this study.

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.
2. Data will be archived on the UMCU server in a research folder. The research folder and the key to the personal data will be accessible by J.H. Coert or the DHS data manager. Therefore, it easily findable. The final dataset will be a SPSS file in Castor containing all the data collected. The final SPSS file will have clear descriptions of each variable and therefore it will be easy to be reused.

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. Part of the (meta)data package will be published in DataverseNL. See the link for more info: https://intranet.umcutrecht.nl/connect/DIT/Alles%20over%20software%20en%20systemen/Paginas/DataverseNL-Introduction.aspx.

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. My peers will be reusing all research data in the final dataset to generate new research questions.
2. The raw data can be of interest for other researchers 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)

1. 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 and always in accordance with the original informed consent provided.

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 upon completion of the project

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

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. Part of the (meta)data package will be published in DataverseNL. See the link for more info:
https://intranet.umcutrecht.nl/connect/DIT/Alles%20over%20software%20en%20systemen/Paginas/DataverseNL-Introduction.aspx.