Plan Overview

A Data Management Plan created using DMPonline

Title: Prevalence of Pain and assessment of aesthetic outcomes after a microsurgical lower extremity reconstruction

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Funder: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

Rationale: The aesthetic outcome of a lower leg reconstruction can be related to the kind of free flap that is used for the reconstruction. The aesthetic outcome, the presence of lymphedema and the presence of pain have not been studied yet. Objective: To compare the patient reported aesthetic outcome of leg reconstructions with a fasciocutaneous flap to reconstructions with a muscle flap. Our secondary objective is to assess the presence of pain and their general health in these patients. Study design: Observational cohort study. Study population: Patients that had a free flap reconstruction of their leg who are older than 16 years old. Main study parameters/endpoints: Aesthetic patient reported outcomes in patients with a lower leg reconstruction. Assess the general health status and the prevalence of pain in these patients.

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Copyright information:

relationship to, your project or proposal

Prevalence of Pain and assessment of aesthetic outcomes after a microsurgical lower extremity reconstruction

1. General features

1.1. Please fill in the table below. When not applicable (yet), please fill in N/A.

DMP template version	27 (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	PALLER
Name Research Folder	xx-xxx_PALLER
Name Division	Heelkundige Specialismen
Name Department	Plastische Chirurgie
Partner Organization	Radboud UMC, Maastricht UMC
Start date study	01-05-2022
Planned end date study	01-05-2023
Name of datamanager consulted*	Dax Steins
Check date by datamanager	08-03-2021

1.2 Select the specifics that are applicable for your research.

- Non-WMO
- Use of Questionnaires
- Multicenter study
- Observational study

This will be a Dutch multicenter study between the following hospitals UMC Utrecht, Radboud MC, Maastricht UMC and Medisch Spectrum Twente. UMC Utrecht, Maastricht UMC and Medisch Spectrum Twente do not have an approved nWMO protocol yet. Radboud already has an approved nWMO protocol and they are going to include our aesthetic questionnaire. Data will be collected by questionnaires send out by Castor EDC, a secured and user-friendly web-based clinical data management platform.

2. Data Collection

2.1 Give a short description of the research data.

Onderzoeksdoel: To compare the patient reported aesthetic outcome of leg reconstructions with

a fasciocutaneous flap to reconstructions with a muscle flap. Our secondary objective is to assess their general health, quality of life and the presence of pain in these patients.

Onderzoekspopulatie: The study population consists of patients who have undergone a lower leg reconstruction using a free flap aged 16 years or older at the UMC Utrecht, Radboud UMC, Maastricht UMC, or Medisch Spectrum Twente between 1990 and 2020.

Participants are once invited to complete five short questionnaires in Castor EDC. Castor EDC is a secured and user-friendly web-based clinical data management platform, enabling researchers to securely capture data from patients. Furthermore, we will analyse their medical records for details on the etiology, type and location of reconstruction, Gustilo classification, follow-up duration, and postoperative peripheral nerve block. This data will be extracted from HIX for the patients that have undergone an operation after 2015. For the patients before 2015, these data will be collected from the DARE-database. The DARE-study was performed in 2016 at the UMC Utrecht and contains a database of data on lower extremity amputations and reconstructions.

Dataflow:

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	100	VAS-score	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	100	Aesthetic questionnaire	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	100	SF-36	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	100	LEFS	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	100	EQ-5D-5L	Castor	Questionnaire, quantitative	.sav	0-10 GB
Human	100	HIX (after 2015) or DARE database (before 2015)	Castor	Quantitative	.sav	0-10 GB

2.2 Do you reuse existing data?

- Yes, please specify

Details on the etiology, type and location of reconstruction, Gustilo classification, follow-up duration, postoperative peripheral nerve block, duration of wound healing, lap necrosis, donor site complications and reoperations of patients who have undergone surgery before 2015, will be collected from the DARE-database. The DARE-study was performed in 2016 at the UMC Utrecht and contains a database of data on lower extremity amputations and reconstructions.

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	Principal investigator, research team, datamanager
Personal data	Principal investigator, 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 of which two are not calibrated. At the end of the study data will be extracted from Castor to SPSS.
Data will be collected by E. List and D. Krijgh. 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 D.D. Krijgh (free)
2.	Design of eCRF			by D.D. Krijgh (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 consulted the division 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?
Name and email address of participants	To be able to invite participants for taking part in the research and to send them questionnaires
Age, sex, length, weight, comorbidities, etiology, type and location of reconstruction, Gustilo classification, and follow-up duration	To be able to perform a multivariate analysis on the data.
Aesthetic outcome	To compare leg reconstructions with a fasciocutaneous flap to reconstructions with a muscle flap.
Lower extremity functionality	To compare leg reconstructions with a fasciocutaneous flap to reconstructions with a muscle flap.
General health	To compare leg reconstructions with a fasciocutaneous flap to reconstructions with a muscle flap.
Quality of life	To compare leg reconstructions with a fasciocutaneous flap to reconstructions with a muscle flap.
Pain in the lower leg	To compare leg reconstructions with a fasciocutaneous flap to reconstructions with a muscle flap.

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.

Data of patients will be encoded and stored in our web-based research database (CASTOR). Patients are assigned a code based on the order of inclusion. These codes will be used in the database, on the case record forms of the different imaging modalities and during the data-analysis. The coordinating researcher will maintain a coding list.

Names of patients or other patient identifiers will not be visible in scientific publications. Digital data are protected by our local hospital information system. This will also protect the data to outside the hospital. Study data will be stored for 15 years after finishing the study.

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 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 already collected data from the research database can not be done because this will result in a research bias.

Right of rectification: If the patient decides to use his/her right of access and demonstrable errors in his/her data are shown, the patient has the right to have them corrected.

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.
2. In case we need to transport personal data with colleagues, we use Surffilesender with encryption.
3. We are going to have a Research Agreement and/or Data Transfer Agreement with the Radboud UMC Nijmegen, Maastricht UMC and Medisch Spectrum Twente. Only pseudoanonymized data will be securely shared using Castor EDC. The agreement is stored at location: with Tamara Marees

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. 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.
2. UMC Utrecht is initiator of this multicenter study. All data and documentation collected by the UMC Utrecht will be stored in the secured Research Folder Structure of the UMC Utrecht. Importantly, personal data is stored separately from other research data and adequate access and control rights are in place. In other participating sites, data and documentation will be stored accordingly

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, I prepared a codebook of my research database. We will use standard metadata from Castor.

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. 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 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 (SPSS). 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 W. Maarse, D. Krijgh and E. List, 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. 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.

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.

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.

In case of future collaborations with other hospitals we can share the data after a data sharing contract is signed. We will not make them publicly available.