Plan Overview

A Data Management Plan created using DMPonline

Title: THRILLER Registry: crural and pedal pathology

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Template: UMC Utrecht DMP

Project abstract:

Rationale: The prevalence of peripheral arterial disease (PAD) is still rising. The end stage of PAD is critical limb ischemia (CLI) and is associated with high amputation- and mortality rates and low quality of life. Despite international guidelines, there is still clinical variation in the treatment of CLI. Objective: To investigate the best endovascular treatment modality in patients with CLI based on arterial pathology below the knee Study design: A prospective multi-center cohort study. Study population: Patients (≥ 18 years) with CLI based on arterial pathology below the knee. Main study endpoints: The primary endpoints are limb salvage and primary patency. Limb salvage is defined as freedom from major amputations, i.e. amputations above the ankle. Primary patency is defined as freedom from clinically-driven target lesion revascularization (CD-TLR) and a significant restenosis on imaging. Nature and extent of burden: No additional actions are required and no additional risks are taken by included patients. This study will not influence patient care.

ID: 63250

Start date: 01-02-2021

Last modified: 23-03-2021

THRILLER Registry: crural and pedal pathology

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	THRILLER
Name Research Folder	2020.0609_THRILLER
Name Division	Surgical specialties
Name Department	Vascular surgery
Partner Organization	NWZ Alkmaar
Start date study	TBD
Planned end date study	
Name of datamanager consulted*	Dax Steins
Check date by datamanager	05-01-2021

1.2 Select the specifics that are applicable for your research.

- Multicenter study
- Observational study
- Prospective study
- Non-WMO

The following centers will participate in this multicenter prospective Dutch registry :

1. Isala hospital, Zwolle
2. Jeroen Bosch hospital, ‘s-Hertogenbosch
3. Maasstad hospital, Rotterdam
4. Noordwest Ziekenhuisgroep Alkmaar
5. Sint Antonius hospital, Nieuwegein
6. Elisabeth-TweeSteden hospital, Tilburg
7. University Medical Center, Utrecht

2. Data Collection

2.1 Give a short description of the research data.

The aim of this prospective multicenter Dutch registry is to collect on a broader scale health care data on patients with CLI (Critical Limb Ischemia) based on arterial pathology below the knee. In doing, this register can enable future research to investigate the best endovascular treatment modality in these patients.
Only adult patients (≥ 18 years) with CLI based on arterial pathology below the knee will be eligbile for this registry.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	1000	EPD (HiX)	Castor EDC	Quantitative	.sav / .xlsx	11-100GB

2.2 Do you reuse existing data?

- No, please specify

We shall not reuse any existing data as this is a new prospective registry.

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

1. Local research members will only have access to local data of this registry (including personal data). Only the coordinating investigator has access to all the data of different centers. The eCRF of this registry is made in Castor EDC. After inclusion, each patient will receive a unique identifier after which all research members are authorized to work with the pseudonymized research data. The key-linking table to re-identify included patients will not leave the local hospital.

Type of data	**Who has access**
Direct identifying personal data	Local investigators (including local PI), Coordinating investigator, Local datamanager
Key table linking study specific IDs to Patient IDs	Local investigators (including local PI), Coordinating investigator, Local datamanager
Pseudonymized data	The entire research team

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 (license of NWZ Alkmaar). In the eCRF, skips and validation checks are built in.

#	**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")	**Sponser** (NWZ)	**Other** (specify)
1.	Time of datamanager	X		
2.	Design of eCRF		X	
3.	Data Capture Tool license fee		X	
4.	Storage		X	
5.	Archiving			X

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.

The collection of coded data from all local hospitals is owned by the sponsor (Noordwest Ziekenhuisgroep Alkmaar). If local site investigators want to make use of the collected data, they can file a request to the sponsor.

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 data manager and I do not need 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?**
Demographics: gender, age, BMI	To describe our study population
Medical history: smoking, hypertension, hyperlipidemia, diabetes (medication dependency), cardiovascular disease, cerebrovascular disease, VTE, carotid artery disease, antithrombotics, renal insufficiency, dementia, ASA grade, living status, functional status. PAD history: previous PAD revascularizations or amputations. Clinical classification scores: Fontaine, Rutherford, WIfI classification. Radiology: ankle-brachial index (ABI), Duplex/MRA/CTA reports, number of target lesions (TL), stenosis vs occlusion, de novo/instent/in bypass, TL length. Lab: Hb, L, CRP, kreat, cholesterol, LDL, HDL, triglycerides, HbA1c	To describe our study population
Intervention general: urgency, access site, largest sheath size, type of anaesthesia, heparin administrations, number of TL, stenosis/occlusion, lesion length, endovascular technique (diameter en length device, inflation time, no of inflations). Simultaneous interventions: endovascular, open, amputations. Complications: procedural success, acute occlusion, distal embolization, perforation, myocardial infarction, CVA, death. Anatomy: outflow vessels before and after intervention, TASC & GLASS classification. Postoperative phase: ABI, WIfI classificiation, hospital stay duration, antithrombotics, complications: severe bleeding, pseudoaneurysm, SSI, contrast-induced nephropathy. Re-interventions. Follow-up: number of visits, antithrombotics, Fontaine, Rutherford, WIfI, ABI, duplex/MRA/CTA reports, complications: major adverse cardiac events (MACE), restenosis/-occlusion, reinterventions, amputations (major/minor)	To answer future the research questions

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

- Other, please explain

Broad consent will be obtained of all patients at the outpatient clinic. Ideally before surgery, but if forgotten after surgery on the ward or outpatient clinic. In this informed consent patients will declare that they agree with their health care data being used by the current research team for future research based on the registry.

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

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 Access	We have to refuse participant's right of access, because this would make the research impossible to conduct given the large number of participants (n=1000).
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 make use of a certified Electronic Data Capture (EDC) tool (Castor). No personal data will be used in the EDC. 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.

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

The collection of coded data from all local hospitals is owned by the sponsor (Noordwest Ziekenhuisgroep Alkmaar). We will not transport any personal data outside the network drives of the local hospital (e.g. UMC Utrecht).

4. Data Storage and Backup

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

NWZ Alkmaar is initiator of this multicenter study.
All (meta)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.

During data collection, automatic backups will be made in the Electronic Data Capture Tool Castor. Above that, a data export will be periodically performed. 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.

For the data collected in Castor, I prepared a codebook of my research database. We do not use metadata standards yet.

5.2 Describe your version control and file naming standards.

We will keep track of changes using descriptions of changes per datestamp for each file in a separate Word document.

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

Not applicable.

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, 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 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 local data package will be stored at the Research Folder Structure of the local institution (e.g. UMC Utrecht) and is under the responsibility of the Principal Investigator of the research group.
The collection of pseudonymized data from all local hospitals is owned and stored by the sponsor (Noordwest Ziekenhuisgroep Alkmaar). Other participating hospitals may be given access to this collection of data if they request.

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

Netherlands Trial Register (ID: NL9192)

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.

Data collect in this register will be used to answer future research questions in the field op ...?

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.

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 after completion of project (with embargo)

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

Still to be determined.