Plan Overview

A Data Management Plan created using DMPonline

Title: Interventions Following Fractures of the Spine In the Aged Patient, Linked to Quality of Life Outcomes

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Funder: UMC Utrecht

Template: UMC Utrecht DMP

Project abstract:

Rationale: With the increasing longevity and incidence of spinal trauma in the elderly, it becomes of greater importance to understand the differences with the younger patients. Treatment often comes with more invasive surgeries of longer duration and prolonged recovery, possibly negatively effecting the health related quality of life (HRQOL) outcomes of the elderly patient in the short- and long term. - We hypothesise that spinal balance following treatment for a traumatic spine injury in the elderly patients has little effect on HRQoL outcome. - We hypothesise that surgical treatment of spinal trauma in unbalanced elderly does not require extensive correction of spinal balance for acceptable HRQoL outcomes, as compared to balanced elderly patients. Objective: The present study aims to explore the effects of spinal balance, and restoration of spinal balance, on HRQOL outcomes following treatment the elderly patient presenting with spinal trauma. Study design: Multi-centre prospective cohort study (UMCU, MUMC+, Zuyderland and the Diakonessenhuis) Study population: Elderly (≥55 years) patients with traumatic spine injury sustained between 1-1-2000 and 31-12-2020, with an ASIA score C, D or E. Main study parameters/endpoints: Age, spinal balance, HRQOL outcomes (AOSpine PROST, ODI, NDI, EQ-5D). Nature and extent of the burden associated with participation, benefit and group relatedness: The data of this study will be gathered from the UMCU, MUMC+, Zuyderland and Diakonessenhuis. Patients will receive standard patient care, and are asked to give informed consent. Patients that are included gain no direct benefit from participation in this study, however we aim to improve care for future patients presenting with a spinal trauma.

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End date: 31-12-2022

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Copyright information:

Interventions Following Fractures of the Spine In the Aged Patient, Linked to Quality of Life Outcomes

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	iFALL
Name Research Folder	xx-xxx_iFALL
Name Division	DHS
Name Department	Orthopedic Surgery
Partner Organization	-
Start date study	Date of approval from the METC
Planned end date study	31-12-2022
Name of datamanager consulted*	Dax Steins
Check date by datamanager	30-12-2020

1.2 Select the specifics that are applicable for your research.

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

Other participating centres for this study are: Diakonessenhuis (Utrecht) , Zuyderland (Heerlen), MUMC+ (Maastricht). All of these centres are located in the Netherlands.

2. Data Collection

2.1 Give a short description of the research data.

This study will concern a multi-center cross-sectional prospective design, the sample will consist of elderly (≥55 years) patients presenting with a spinal fracture (ASIA score of C, D or E) from the date of METC approval until 31-12-2022.

Primary Objective: to examine whether HRQoL outcomes differs for spinal balance (balanced vs non-balanced), following treatment of traumatic spinal injury after one year follow-up. And whether this effect differs per fracture type.

Pseudonymized data will be gathered from multiple Dutch hospitals (UMCU, MUMC+, Diakonessenhuis and the Zuyderland). After inclusion, a unique identifier based on the study-site will be assigned to each patient. All necessary clinical parameters will be extracted from the Electronic Health Records (EHRs, HiX) and entered into a web-based data management application (the UMCU endorsed system Castor EDC) by members of the research team at each site.

At three and twelve months follow-up: patients will receive a full-spine radiographic measurements and asked to fill out 4 HRQoL questionnaires. The questionnaires will be automatically send by Castor EDC.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	200	EPD (HiX)	Castor	Quantitative	.xlsx / .csv / .sav	0-10 GB
Human	200	AO PROST Questionnaire	Castor	Quantitative	.xlsx / .csv / .sav	0-10 GB
Human	200	EQ-5D-5L Questionnaire	Castor	Quantitative	.xlsx / .csv / .sav	0-10 GB
Human	200	VAS back- and leg pain	Castor	Quantitative	.xlsx / .csv / .sav	0-10 GB
Human	200	Radiographic outcomes	PACS / Castor	Quantitative	.xlsx / .csv / .sav	0-10 GB

2.2 Do you reuse existing data?

- No, please specify

In this prospective study, we use data from HiX and collect pseudonymized data via Castor by all the participating centres.

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

Pseudonimyized data will be collected in Castor EDC. Only members of the UMCU research team will have access to all the pseudonymized data (each participating center). The data is pseudonymized with a unique identifier--study-specific study ID.

Type of data	Who has access
Direct identifying personal data	PI, Research team, DHS Datamanager
Key table linking study specific IDs to Patient IDs	PI, Research team, DHS Datamanager
Pseudonymized data	Research team

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

The informed consent received from the study participants will be stored on the internal drive and signed forms will be stored in a locked place of the hospital where the patient is included. Clinical data is manually collected from the electronic health records. New study data will be collected using an HRQoL questionnaires via Castor at 3-12 months follow-up. Using Castor, data will be entered in a pseudonymized manner in a shared database. Following data gathering in Castor, processing will occur using SPSS and Excel and the subject ID, leaving out any personal information of the subjects. If there is missing data, subjects will be contacted again and asked for the missing data. Outliers will be analysed and corrected if possible, if the outlying value is legit then it will be included in analysis. Eventually the pseudonymized data will be joined together for analyzation purposes. The principal investigator, physician and the researcher for each institution will have access to the research data. Data protection will be according the EU General Data Protection Regulation and data will be stored on the research network disc of the division for 15 years following the end of the study.

#	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.	Data Capture Tool license fee	x		
2.	Time of datamanager	x		
3.	Questionnaire license fee	x		
4.	Informed consent paper	x		
5.	Storage	x		
6.	Archiving	x		

Explanation.

1/3. License fee for using Castor

6. 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 the already existing 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 for a multicenter study. 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)adress	To be able to invite participants for taking part in the research and to be able to mail them the informed consent form. We need the email for the HRQoL questionnaires at 3 and 12 months after trauma.
Gender, age	To describe our study population
Date of trauma, date of follow-up	To determine the follow-up duration
Comorbidities, ISS classification, other spine surgeries	To determine the health status of the patient, and identify any potential confounders
Fracture level, type of fracture, spinopelvic parameters	To determine the fracture classification on radiographs or scans
HRQoL outcomes (AOSpine PROST, EQ-5D, VAS leg pain, VAS back pain,	To determine the succes of the chosen type of treatment

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

- Study-specific informed consent

Eligible subjects will be asked for an informed consent, and included when filled in.

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

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. We make use of informed consent, were 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, due to the possibility that a specific sub-group might request for removal of data and therefore the possibility exists that this will interfere with the results. 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.

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.

In case we need to transport personal data with colleagues, we use Surffilesender with encryption.

4. Data Storage and Backup

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

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. We will need +/- 10 GB storage space, so the capacity of the network drive will be sufficient. 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.
Moreover, Castor is used to enter data in a shared database and to access this data from all of the participating centres. The

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

All (research) data that is stored on UMC Utrecht networked drives, will be backed up twice a day by the division IT (dIT). The data that is stored in the other centres will be stored accordingly.
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.

For the data collected in Castor, I prepared a codebook of my research database. We do not use metadata standards yet. During data gathering, we would like to know by who the data was added to Castor, on which date this happened and in which centre it was

added. For each subject, we would like to know when the radiographs where assessed for type of spinal fracture, in which program this was done and by whom this was done.

Moreover, each value and label of the database will be given a clear and self-explanatory name. If we do use abbreviations then we will provide a list of definitions.

Finally, Castor will provide standard metadata regarding the database.

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 (iFALLVersDoc.txt).

6. Data Analysis

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

I have written an analysis plan, integrated in the study protocol, 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 stored in the project folder, so it is findable for my peers.

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.

In view of the regulation for Clinical Trials, I need to store all data for at least 15 years with the goal to be able to go back to patient level.

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 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.

When this data leads to a published article, we will be using a DOI-code and will add the code to the plan as soon as it is given.

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.

The raw data can be of interest for other researchers or for spin off projects. For the procedure of how the data can be reused, and accessed by other researchers, we refer to 8.2.

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.

In case the Castor database is shared with other researchers, the full database will be made available for them. However, of the metadata we will exclude any researcher names and institutions.

8.4 Describe when and for how long the (meta)data will be available for reuse

- Other (please specify)

Data will be available for reuse in the participating institution. If a request to reuse any of the data is granted, we will provide the requesting party the data as described in 8.3. Requests to reuse the data will be possible for the duration of the data-storage period of 15 year (as mentioned in 7.2).

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

See 8.4