Plan Overview

A Data Management Plan created using DMPonline

Title: Influence of Age in the Decision Making Process in Spinal Trauma, Following the AOSpine Classification System and Schnake classification

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Template: UMC Utrecht DMP

Project abstract:

Rationale: Classification systems for spinal fractures, like the AOSpine classification, have incorporated several patient modifiers over the past few years. However, although increasingly important, age is rarely considered in these classification systems. Until now, the role of age in the decision making process for patients with a spinal fracture has not yet been investigated. 1. We hypothesise that patients aged ≥65 years more often receive a conservative treatment for the same type of fracture, compared to patients aged <65 years. 2. We hypothesise that the elderly patient presenting with osteoporotic fractures often receive a more conservative treatment using the AOSpine classification if compared to the Schnake classification Objective: The present study aims to explore the role of age in the decision making process for treatment in patients presenting with a spinal fracture, comparing the elderly (≥55) and younger (<55) patients. Study design: Multi-centre retrospective, cross-sectional cohort (UMCU, MUMC+, Zuyderland and the Diakonessenhuis) Study population: Adult (≥18 years) patient with traumatic spine injury sustained between 01.01.2004 and 31-12-2020, with an ASIA score C, D or E. Patients are divided in age groups (18-55 years and ≥55 years). Main study parameters/endpoints: Age, AOSpine classification of fracture, OF Schnake classification , current comorbidities (osteoporosis, cardiovascular disease, lung disease, cancer, diabetes, neurological), treatment received Nature and extent of the burden associated with participation, benefit and group relatedness: The data of this study will be gathered in the UMCU from the database of a previous (ongoing) study ‘PTDEF HRQoL’ by de Gendt et al.. The data from the MUMC+, Zuyderland and Diakonessenhuis will be gathered by setting up a new database, following similar steps as the already existing database in the UMCU. 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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Influence of Age in the Decision Making Process in Spinal Trauma, Following the AOSpine Classification System and Schnake classification

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)*	N/A
METC number *(only for human-related research)*	TBD
DEC number *(only for animal-related research)*	N/A
Acronym/short study title	AOLD
Name Research Folder	AOLD
Name Division	N/A
Name Department	Orthopedic Surgery
Partner Organization	-
Start date study	The date of the METC approval
Planned end date study	31.12.2020
Name of datamanager consulted*	Dax Steins
Check date by datamanager	

1.2 Select the specifics that are applicable for your research.

- Multicenter study
- Retrospective 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.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human UMCU(2018-2020)	Estimated 50-100	Research Data Platform (RDP)	Research Data Platform (RDP)	Quantative	.sas7bdat	0-10 GB
Human UMCU (2004-2018, UMCU)	200-300	METC 19-457	Excel	Database	.xlsx	0-10 GB
Human Diakonessenhuis (2004-2020)	Estimated 100-300	Local RDP or manually selected using the Electronic patient files	Castor	Database	.csv	0-10 GB
Human Zuyderland (2004-2020)	Estimated 100-300	Local RDP or manually selected using the Electronic patient files	Castor	Database	.csv	0-10 GB
Human MUMC+ (2004-2020)	Estimated 100-300	Local RDP or manually selected using the Electronic patient files	Castor	Database	.csv	0-10 GB

Primary Objective: Exploring the role of patients age in the decision making process by comparing the treatment given and the type of fracture using the AOSpine classification systems for vertebral fractures.
Secondary Objective(s):Comparing the AOSpine classification to the Schnake classification in osteoporotic fractures.

This study will concern a multi-center cross-sectional retrospective design, the sample will consist of elderly (≥55 years) patients presenting with a spinal fracture (ASIA score of C, D or E) between 01-01-2004 and 31-12-2020. Data will be gathered from multiple hospitals (UMCU, MUMC+, Diakonessenhuis and Zuyderland). For this study, a research database from a previous study in the UMCU will be re-used (METC 19-457). This Excel database (2004-2018) consists of eligible research data from patients whom have given written informed consent in the past. Data from this database will be transferred to a newly made shared Castor database. Patients for the period 2018-2020 will be given an information letter, asked for informed consent and included upon agreement. Their data will be directly added to the Castor database. In the other centers, eligible patients will be recruited as mentioned in 7.2 and their data will be added to the Castor database.

2.2 Do you reuse existing data?

- Yes, please specify

In this retrospective study we use existing data from a database created for the study PTDEF_HRQoL (METC 19-457).

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

Type of data	Who has access
Direct identifying personal data	Research team with care relationship to patient. PI, Datamanager
Key table linking study specific IDs to Patient IDs	PI, Datamanager
Pseudonymized data	Research team

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

#	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.	Storage	x		
3.	Archiving	x		
4.				
5.				

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 that is gathered in other centres will be entered in the shared Castor database, where pseudonymisation takes place simultaneously. The data is collected in a relatively large patient group and is very valuable for further, broader studies. 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 adress	To be able to invite participants for taking part in the research and to be able to mail them the informed consent form.
Gender, age	To describe our study population
Date of trauma, date of follow-up	To determine the follow-up duration
Comorbidities, ISS classification	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
Treatment, complications or reoperations	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 from a database of an ongoing study (METC 19-457) will be included in this study. The in- and exclusion criteria of this study assures inclusion of all patients that are eligible for inclusion in our study from 2004 until 2018. The signed informed consent for the study (METC 19-457) possibly is eligible for this study, if a specific box is ticked on the form:

*'Ik geef x **wel***
*☐ **geen** toestemming om mijn persoonsgegevens langer te bewaren en te gebruiken voor toekomstig onderzoek op het gebied van wervelbreuken*
If the above is the case, no new informed consent will be sent. If this is not the case, we will sent new informed consent form.

Patients eligible for inclusion in the UMCU in the period 2018 to 2020, will be asked for informed consent, either digital or by paper via mail. Patients in the MUMC+, Zuyderland and Diakonessenhuis will be recruited following a similar procedure as for the database of the ongoing study (METC 19-457). Patients who are eligible for inclusion receive an information letter and informed consent with a return envelope. For questions from the subject, contact with an Orthopaedic surgeon is possible by telephone. If a patient agrees for inclusion, the signed the informed consent is sent back to the hospital, after which they received a copy of the informed consent and will be assigned a study ID.

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.

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.

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.

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.

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 (AOLDVersDoc.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 data extracted from Castor, the study protocol describing the methods and materials, the script to process the data, the scripts leading to tables and figures in the publication, if needed 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