The survival of patients salvaged with an emergency thoracotomy

A Data Management Plan created using DMPonline

Creators: Ali Sam, First Name Surname

Affiliation: UMC Utrecht

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Template: UMC Utrecht DMP

Project abstract:

Despite guidelines there still is an ongoing debate and a search for predictive survival factors for patient who require an emergency thoracotomy. This study aims to examine the efficacy of the emergency thoracotomy at a Dutch level 1 trauma center and attempt to aid the search for variables which can help predict the survival of these patients in extremis, thereby improving the decision making process in the ED.

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1. General features

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	ET
Name Research Folder	xx-xxx_ET
Name Division	Heelkundig Specialismen
Name Department	Traumatologie
Partner Organization	n/a
Start date study	
Planned end date study	
Name of datamanager consulted*	Dax Steins
Check date by datamanager	05-01-2021

- Non-WMO
- Retrospective study
- Monocenter study

2. Data Collection

Objective : The primary objective is to determine the survival rate (both short term and long term) of our cohort. The secondary objective is to determine which factors could help to predict the survival of patients treated with an emergency thoracotomy.

Study population: All adult patients (≥ 18 years at time of the injury) who were treated at the University Medical Center Utrecht (UMCU) with an emergency thoracotomy between 01-01-2008 and 31-12-2020 will be included.

For this retrospective study, research data will be provided by the Dutch trauma registery: Traumzorgnetwerk Midden-Nederland (TZMN). Besides additional trauma data, TZMN has also access to UMC Utrecht's electronic health records (HiX). Thus, all research data will be provided by TZMN.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	140	Trauma registry (TZMN)	Excel	Quantitative	.xlsx	0 - 10GB
Human	140	EPD (HiX)	Excel	Quantitative	.xlsx	0 - 10 GB

- Yes, please specify

We will reuse existing patient data from the EPD and the trauma registry.

My division datamanager receives data from TZMN that contains direct identifying personal data (e.g. date of birth). After 4-eyes controle, the dHS datamanager will encode the data with a key-linking table. The key table linking study specific IDs to patient IDs is available to the datamanager and members of the research team with a care relationship to the patient. Other members of the research team receive a pseudonymized dataset and have no access to direct personal data or the key table.

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

Research data from patients will be collected in an Excel spreadsheet. Data quality will be checked by a research members with a care relationship to the patient. Data collection will be frozen before analysis. SPSS Statistics will be used as statistical software tool.

#	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		

#	Type of costs	Division ("overhead")	Funder	Other (specify)
1.	Time of datamanager	X		
2.	Storage	X		
3.	Archiving	X		

UMC Utrecht is and remains the owner of all collected data for this study. 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)

- Yes, go to next question

I will process personal data. 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.

Which personal data?	Why?
Gender, age, comorbidities	To describe our study population
Trauma specific data (date and mechanism)	To answer the research question
Laboratory data	We need the results to help answser the research question
Resuscitation data	We need the results to help answser the research question

- No objection, please explain

There is no study-specific informed consent. Because of that, we will make use of the no-objection check prior to data collection.

The data will be pseudonomyzed. An authorized person manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data.

We will request and use a special research folder.

We have a Data Transfer Agreement with TZMN. SURFdrive, a secure institutional cloud storage, will be used to share data from TZMN via a encrypted URL-link. No data will be transported outside the UMCU network drives.

4. Data Storage and Backup

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.

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

For the data collected, we will prepare a codebook of the research database. We will not make use of any metadata 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.

6. Data Analysis

I have not yet written an analysis plan. But in this analysis plan, I will state why I will use which data and which statistical analysis we plan to do in which software. The analysis plan will be stored in the project folder, so it is findable for my peers.

7. Data Preservation and Archiving

The data package (i.e. our research/project folder) 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.

Data and documentation needed to reproduce findings from this non-WMO study will be stored for at least 15 years.

After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure on the L:drive (xx-xxx_ET) 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.

We have not registered this study externally. As soon as we have a DOI-code or have published a dataset in a public repository we shall update this section.

8. Data Sharing Statement

For now, just my internally. Our department will be reusing all research data in the final dataset to generate new research questions. We shall determine at a later stage of this study on what scale ("Open Science") we intend to share this research data.

To be determined.

To be determined.

To be determined.

As pointed out earlier we do not yet know. To be determined.