Plan Overview

A Data Management Plan created using DMPonline

Title: TORCH: Tranexamic Acid to Prevent Operation in Chronic Subdural Hematoma

Creator: Steven Immenga

Principal Investigator: s.immenga@amc.nl, Prof. dr. W.P. Vandertop

Data Manager: s.immenga@amc.nl

Affiliation: University of Amsterdam (Universiteit van Amsterdam)

Funder: ZonMw (Nederlands)

Template: Datamanagement ZonMw

ID: 22675

Last modified: 11-10-2021

TORCH: Tranexamic Acid to Prevent Operation in Chronic Subdural Hematoma - Data management ZonMw (English version)

1. General features of the project and data collection

1.1 Project leader contact details

Academic Medical Center
Department of neurosurgery
Meibergdreef 9
1105 AZ Amsterdam
The Netherlands

1.2 I have composed my DMP with the assistance of a data management expert. List his or her name, function, organisation/department, phone number and email address.

- The expert is connected to my department or institution

Mr. R.A. Scholte
Head datamanagement
Department Clinical Research Unit
Meibergdreef 9
1105 AZ Amsterdam
T: +31 20 5667649
E: r.a.scholte@amc.nl

1.3 In collecting data for my project, I will do the following:

- Use existing data (please specify)
- Generate new data

Usage of health care data from the electronical medial files. Collection of new data by prospective follow-up of study participants.

1.4 In my research, I will use:

- Exclusively quantitative data

1.5 I will be reusing or combining existing data, and I have the owner's permission for using or combining their data.

- Yes, I have permission to use the data

Patient data from the medical file; the patient gives informed consent for the collection of these data.

1.6 In collecting new data, I will be collaborating with other parties.

- No

1.7 I am a member of a consortium of 2 or more partners. Clear arrangements have been made regarding data management and intellectual property. (also consider the possible effect of changes within the consortium on issues of data management and intellectual property)

- No, I am not working with 2 or more partners

The study takes place in the AMC and VUmc. Together both centers form the neurosurgical center amsterdam with one head of department who is also the PI of this study. Possibly more centers will be added to the study; at that moment there will be a contract about datamanagement and intellectual property.

1.8 I can give an estimate of the size of the data collection; specifically, the number of participants or subjects (“n=”) in the collection and its size in GB/TB

- Yes (please specify)

n=140, the total dataset (one or several SPSS files) is at the most 1 gigabyte

1.9 The following end products I will make available for further research and verification (please elaborate briefly)

- Raw data
- Several versions of processed data
- Documentation of the research process, including documentation of all participants
- Data documentation

This study generates a dataset that per participant includes baseline data, randomisation data and the different outcome measurements. The baseline data are mostly data from the medical file. The outcome measurements are study-specific and prospectibely collected data.

1.10 During the project, I will have access to sufficient storage capacity and sites, and a backup of my data will be available. (please elaborate briefly)

- Yes, I will make use of my institution's standard facilities for storage and backup of my data

Standard AMC policy

2. Legislation (including privacy)

2.1 I will be doing research involving human subjects, and I am aware of and compliant with laws and regulations concerning privacy sensitive data.

- Wet Bescherming Persoonsgegevens (Personal Data Protection Act) and the Code of Conduct for Medical Research derived from it; I will register my project with the Dutch Data Protection Authority
- Kwaliteitsborging Mensgebonden Onderzoek (Quality Assurance for Research Involving Human Subjects)
- Wet Medisch-Wetenschappelijk Onderzoek met Mensen (WMO, or Medical Research (Human Subjects) Act); I will submit my project for review by a Medical Research Ethics Committee
- Wet op de Geneeskundige Behandelingsovereenkomst (Medical Treatments Contracts Act)

The central hotline personal data of the AMC has been notified about this project.

2.2 I will be doing research involving human subjects, and I have (a form of) informed consent from the participants for collecting their data.

- Yes (please describe the form this consent takes)
- Yes, and this informed consent allows for the reuse of data (note that in the Code of Conduct for Medical Research, ‘reuse’ is also referred to as ‘further use’)

Informed consent with a patient information letter and the informed consent form which is signed before study participation.

2.3 I will be doing research involving human subjects, and I will anonymise or pseudonymise any privacy sensitive data.

- Yes, the data will be pseudonymised

2.4 I will stick to the privacy regulations of my organisation

- Yes

3. Making data findable

3.1 The data collection of my project will be findable for subsequent research (note: this is a key item, which you should report to ZonMw at the end of your project).

- Yes, it can be found through the search engine of the archive or repository in which it is stored (please specify)
- Yes, it can be found through an online (metadata) catalogue or web portal (please specify)

This project follows the standard policy of the AMC. DataCites metadata scheme will be used in cooperation with the administrator of the AMC data repository Figshare.

3.2 I will use a metadata scheme for the description of my data collection.

- Yes, I will select a metadata scheme from the list published by Datacite (please specify)

This project follows the standard policy of the AMC. DataCites metadata scheme will be used in cooperation with the administrator of the AMC data repository Figshare.

3.3 I will be using a persistent identifier as a permanent link to my data collection (note: this is a key item, which you should report to ZonMw at the conclusion of your project).

- Yes, I will be using the DOI code

This project follows the standard policy of the AMC. At the end of the project a DOI code will be generated.

4. Making data accessible

4.1 Once the project has ended, my data will be accessible for further research and verification.

- Yes, after an embargo period (please explain)

After publication of the study results in an international journal.

4.2 Once the project has ended, my data collection will be publicly accessible, without any restrictions (open access).

- No, there will be access restrictions to my data collection (please explain)

The datafile will be publically available. At moment of request of the data, an evaluation of the requester wll be performed (safety and privacy). These terms of use will be setup together with a jurist and be made available.

4.3 I have a set of terms of use available to me, which I will use to define the requirements of access to my data collection once the project has ended (please provide a link or persistent identifier; also note that this is a key item, which you should report to ZonMw at the conclusion of your project).

- Not yet, my institution will draft a set of terms of use with the help of a legal advisor

These terms will be available before the end of the study.

4.4 In the terms of use restricting access to my data, I have included at least the following:

- Conditions related to data security
- Agreements on methodology
- Collaboration in using the data set, including agreements on publication and authorship
- The sharing of data for commercial purposes, taking into account the provisions of state aid law
- Whether or not the data set may be linked with another data set (for reasons of privacy)
- The manner in which the data set can be accessed
- The permitted period of use of the data set
- The reimbursement of costs, for example in obtaining the data
- A steering committee, programme committee or project leader will be charged with approving data requests
- The approval of the participants allows for further research using this data set

5. Making data interoperable

5.1 I will select a machine actionable data format, which will allow other researchers and their computers to read my data collection.

- Yes (please specify)

Datamanagement with Castor EDC. The dataset is exported to an SPSS file, which will be made available.

5.2 I will select a metadata standard to allow my data collection to be linked to other collections (note: this is a key item, which you should report to ZonMw at the conclusion of your project).

- Yes, I will select a metadata standard from the list published by Biosharing (please specify)

Datamangement with Castor EDC. The dataset is exported to an SPSS file. Outcome measurements will be done with internationally accepted measurement instruments (SF-36, mRS, mNHISS, Barthel, Lawton, MOCA, EG-5D). The stand advies metadata scheme of the AMC will be used.

5.3 I will be doing research involving human subjects, and I have taken into account the reuse of data and the potential combination with other data sets when taking privacy protection measurements.

- Yes, the participants have given their permission for reuse of the data, and the data have been pseudonymised

As many identifiable data as possible will be erases from the dataset. Participants have given informed consent for the reuse of the data. At request for the sharing of study data the privacy of the participants is secured with the terms of use.

6. Making data reusable

6.1 I will ensure that the data and their documentation will be of sufficient quality to allow other researchers to interpret and reuse them (in a replication package).

- I will document the research process (please explain)
- I will perform quality checks on the data to ensure that they are complete, correct and consistent (please explain)
- I will document the software used in the course of the project (please specify)

- the process of the study together with the used software is documented in the study protocol and the Trial Master File
- data is checked for correctness with univariate and multivariate checks

6.2 I have a number of selection criteria, which will allow me to determine which part of the data should be preserved once the project has ended. (see also question 1.9)

- Yes

Pseudonymised data in 1 dataset which includes the baseline data, randomisation data and the outcome measurements. Also the study specific paper questionnaires.

6.3 Once the project has ended and the data has been selected, I can make an estimate of the size of the data collection (in GB/TB) to be preserved for long-term storage or archival.

- Yes (please specify)

1 dataset, maximum 1 gigabyte of data (1 or sevaral SPSS files)

6.4 I will select an archive or repository for (certified) long-term archiving of my data collection once the project has ended. (note: this is a key item, which you should report to ZonMw at the conclusion of your project)

- Yes, and this archive has a data seal of approval (please specify the archive)

The project uses the facilities made available by the AMC. The AMC has a contract with Figshare for the repository; this will be used for this project. With that, the study data will be effectively available and useable.

6.5 Once the project has ended, I will uphold the recommended data preservation period of at least 10 years.

- Yes, in accordance with other guidelines (please explain, and specify the guidelines and the number of years)

20 years according to the Dutch NFU guidelines for research with drugs: quality assurance for research with human study subjects.

6.6 Data management costs during the project and preparations for archival can be included in the project budget. These costs are:

- Unknown (please explain)

The limited costs (because of the small size of the data file) are facturated to the department. The estimated costs are in the budget of the project.

6.7 The costs of archiving the data set once the project has ended are covered.

- Yes (please elaborate)

The costs of the data management and archiving are in the budget of this research project, during and after the project.