Plan Overview

A Data Management Plan created using DMPonline

Title: Pentoxifylline for sepsis in preterm infants

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Affiliation: Other

Funder: ZonMw (Nederlands)

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Project abstract:

Sepsis is a very important cause of death in preterm infants. Survival from sepsis is often related to severe short and long term morbidity. Despite optimal antibiotic treatment, immaturity of the immune system in preterm newborns causes this severe sepsis related mortality and morbidity. There is strong indications that preterm newborns with sepsis could benefit, next to antibiotics, from treatment with pentoxifylline (PTX). PTX which is registered for adults with intermittent claudication, is already used in preterm newborns with sepsis. Knowlegde about optimal dosing is limited. We want to determine how and in what optimal dose PTX should be used in preterm infants suffering from sepsis. Previous clinical studies have already indicated the safety of the drug in preterm infants. We will perform a dose finding study in infants with sepsis and increased inflammation. In this study we will evaluate different dosages, using a continuous reassessment method, of PTX therapy on the recovery of inflammatory biomarkers(CRP, IL-6, TNFa) and clinical recovery. Preterm born infants with a gestational age below 30 weeks and suspected sepsis are eligible for inclusion

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Pentoxifylline for sepsis in preterm infants

1. General features of the project and data collection

1.1 Project leader contact details

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

- The expert is connected to my department or institution (please explain his/hr expertise related to data stewardship)

The DMP was composed with the help of Annelies Ham, PhD, datamanagement coordinator of our department.
Dr. A.C. Ham
Datamanagement coordinator
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1.3 In collecting data for my project, I will do the following:

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

Clinical characteristics of the patients from the EPD will be used in combination with data generated by this research.
The data are registrated in OpenClinica.

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 that.

- Yes, I have permission to use the 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

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)

The expected number of patients for baseline data will be around 100.
In the dose finding trial we plan to include around 30 patients.
Since we will also collect high density physiological data, the size of data will be large but probably <1 GB.

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

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

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

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.

- The Wet Medisch-Wetenschappelijk Onderzoek met Mensen (WMO, or Medical Research (Human Subjects) Act) applies to my project; I will have it reviewed by a Medical Research Ethics Committee. In addition I will comply with the Kwaliteitsborging Mensgebonden Onderzoek (Quality Assurance for Research Involving Human Subjects)
- Gedragscode Goed gebruik van lichaamsmateriaal (Code of Conduct for Responsible Use of Human Tissue)
- Yes, I will involve human subjects in my research. I will comply with the Algemene Verordening Gegevensbescherming (AVG)

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, 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’)

The PIF is evaluated by the Medical Ehtical Board. It contains all neccesary information about the study. Parents of patients will be informed about the study and will be provided with written information about the study. Their informed consent will be asked for participation of their child in the study. A separate consent is asked for future use of the data. Parents will give consent, or not, for the following 3 statements:
'Consent for the further storage of my child’s personal data and retention for future research into the area of on sepsis and pentoxifylline treatment.'
'Consent for my child’s bodily material to be stored after this study and for later use of

this for this study and other studies on sepsis and pentoxifylline treatment, as stated in the information letter.'
'Consent for further research into the relationship between my child's DNA and the amount of pentoxifylline needed.'

2.3 I will be doing research involving human subjects, and I will protect my data against misuse.

- Yes, the data will be pseudonymised. (please explain how this will be done, and by which organisation) and

All included patients will retrieve a unique studynumber. The site (hospital where the patient is included) will have acces to a confidential list with the names and birth dates of the newborns and will be kept there (Identifier file/list).

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. E.g., on a catalogue, a web portal, or through the search enginge of the repository (note: this is key item 3, 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)

DANS easy will be used to archive the data and they will provide an DOI by which the data can be found

3.2 I will use a metadata scheme for the description of my data collection (note: this is key item 7, which you should report to ZonMw at the end of your project).

- Yes, I will use a generic metadata scheme (please specify)

DANS easy makes use of the Dublin Core metadata schema, so that schema will be used.

3.3 I will be using a persistent identifier as a permanent link to my data collection (note: this is key item 1, which you should report to ZonMw at the end of your project).

- Yes, I will be using the DOI code

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)

Data will be available 6 months after the end of the study. In the meantime the first results can be published in (open access) journals.

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)

We intend to share our data with others, but we always need to give permission. In that way will enable the optimal use of the data, bring parties and research groups together and we will stimulate collaboration. Specifically, our data will be available for the registration of pentoxifylline for neonatal sepsis. All data-request will be evaluated by the data committee of the Neonatology department.

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 4, 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

We will contact the legal advice office to help u with setting the terms for re-use of the data.

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

- Conditions related to data security
- 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 reimbursement of costs, for example in obtaining the data
- A steering committee, programme committee or project leader will be charged with approving data requests
- Collaboration in using the data set, including agreements on publication and authorship
- The permitted period of use of the data set

As we still have to draft the terms of use we do not know the exact statements that will be included. Though, the checked statements above will at least be included.

5. Making data interoperable

5.1 I will select a data format, which will allow other researchers and their computers (machine actionable) to read my data collection (note: this is key item 5, which you should report to ZonMw at the end of your project).

- Yes (please specify)

Data files will stored as .csv , and tekst files as .txt.

5.2 I will select a terminology for recording my data (e.g., code, classification, ontology) that allows my dataset to be linked or integrated with other datasets (note: this is key item 6, which you should report to ZonMw at the conclusion of your project).

- Yes, metadata standard (please specify)

ATC codes (medication data)

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

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)

we will puplish the research protocol and data analyses plan. All data will be verified by the research coordinator. Our study and data will be monitored by a qualified CRA.

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 and 6.1)

- No

6.3 Once the project has ended and the data have 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)

The patient characteristics, clinical data, safety data, inflammatory and metabolic profiles will all be stored. The physiological high density data will be extracted from the server and only those data that are relevant for this project will be kept for long term storage. The total size of the data collection will probably be <1GB.

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)

DANS easy will be used.

6.5 Once the project has ended, I will ensure that all data, software codes and research materials, published or unpublished, are managed and securely stored. Please specify the period of storage.

- Yes, in accordance with VNSU guidelines (please specify the number of years)

I will uphold the recommended data preservation period of 15 years.

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

- Amount ..... (please elaborate)

The costs for the datamanager and data storage are covered by the department.

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

- Yes (please elaborate)

These costs will be coverderd by the department of Pediatrics, division of neonatology.