Pentoxifylline for sepsis in preterm infants

A Data Management Plan created using DMPonline

Creators: sinno simons, Rob Taal, PLEASE UPDATE YOUR DETAILS

Affiliation: Other

Funder: ZonMw (Nederlands)

Template: Data management ZonMw-template 2019

ORCID iD: 0000-0001-5219-5696

Grant number: 848082002

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

Last modified: 19-06-2019

Pentoxifylline for sepsis in preterm infants

1. General features of the project and data collection

Sinno Simons, MD, PhD
Pediatrician - neonatologist
Erasmus MC, Sophia Children's Hospital
Department of neonatology
Rotterdam, the Netherlands
s.simons@erasmusmc.nl
phone: 0031-6-41376695

- 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
Division of Neonatology, department of Pediatrics
ErasmusMC - Sophia Children's Hospital
a.ham@erasmusmc.nl
010-7040704

- Generate new data
- Exclusively quantitative data
- No, I will not be reusing or combining existing data
- No
- No, I am not working with 2 or more partners
- 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 (multiple GB)

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

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

2. Legislation (including privacy)

- 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)
- 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)

- 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 will be 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.

- 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.

- Yes

3. Making data findable

- No, I have not yet chosen an archive or catalogue/web portal
- No, I have not yet chosen a metadata scheme
- Yes, I will be using the DOI code

4. Making data accessible

- Yes, after an embargo period (please explain)

Data will be available after the publication of the results in (open access) journals.

- 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..

- Not yet, my institution will draft a set of terms of use with the help of a legal advisor
- A steering committee, programme committee or project leader will be charged with approving data requests
- The reimbursement of costs, for example in obtaining the data
- The permitted period of use of the data set
- Whether or not the data set may be linked with another data set (for reasons of privacy)
- The sharing of data for commercial purposes, taking into account the provisions of state aid law
- Collaboration in using the data set, including agreements on publication and authorship
- Conditions related to data security

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

- Yes (please specify)

Open Clinica will be used as datamanagement system. All data can be extracted in a format readable by other researches.

- Yes, metadata standard (please specify)

ATC codes (medication data)

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

6. Making data reusable

- I will perform quality checks on the data to ensure that they are complete, correct and consistent (please explain)
- I will document the research process (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.

- No
- 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.

- Not yet
- Yes, in accordance with VNSU guidelines (please specify the number of years)

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

- Amount ..... (please elaborate)

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

- Yes (please elaborate)

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