Plan Overview

A Data Management Plan created using DMPonline

Title: Analgosedation after cardiac surgery in infants: A' model-based" nation-wide randomized controlled trial

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Affiliation: Erasmus MC

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Template: Data management ZonMw-template 2019

Project abstract:

Abstract

Introduction

More than half of children with congenital heart disease require a surgical intervention during the first three years of life. Continuous morphine infusion is standard of care to relieve pain after cardiac surgery. Morphine and other opioids have been associated with serious adverse effects such as respiratory depression.

The aim of this study is to determine whether intravenous paracetamol as first-line analgesic would

significantly reduce children’s morphine requirements in after cardiothoracic surgery with cardiopulmonary bypass.

Design, Setting, and Patients Multi-center, randomized, double-blind controlled study. Two-hundred patients younger than three years old undergoing cardiac surgery with cardiopulmonary bypass were included between March 2016 and July 2020. Patients were randomly assigned to either a continuous morphine arm or an intermittent intravenous paracetamol arm and received the????. In both study arms rescue morphine was available on the guidance of the validated pain assessment instruments. Patients in both study arms received a loading dose of morphine at the end of surgery.

Main Outcome Measures The primary outcome was cumulative morphine dose (study and rescue dose) in the first 48 hours postoperative in mcg/kg. Secondary outcomes were pain scores and occurrence of morphine-related adverse effects.

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Analgosedation after cardiac surgery in infants: A' model-based" nation-wide randomized controlled trial

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)

Drs. Annelies Ham, datamanager
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Research suite ErasmusMC rotterdam

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

- Generate new data

1.4 In my research, I will use:

- A combination of quantitative and qualitative data

Prospective data analysis in a randomised controlled trial

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

- No, I will not be reusing or combining existing data

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

- Yes, we have reached agreements on the user rights of the data used in the project
- Yes, I will collect the new data in conjunction with other researchers or research groups

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)

- Yes, clear arrangements have been made regarding data management and intellectual property through a consortium agreement

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)

208 patients

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

- (Several versions of) processed data
- Biobank
- 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

Data is collected in open clinica ecrf and is stored on the server of the ErasmusMC and open Clinica server.

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.

- Gedragscode Goed gebruik van lichaamsmateriaal (Code of Conduct for Responsible Use of Human Tissue)
- Wet op de Geneeskundige Behandelingsovereenkomst (Medical Treatments Contracts Act)
- 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, 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 (please describe the form this consent takes)

The PIF was evaluated by the medical ethical board in the Netherlands (ErasmusMC Rotterdam). It contains all necessary information about the trial. Parents of patients will be informed about the trail and will be provided with written information about the study. In this informed consent parents will be asked for participation of their child in this study whereby the collected data will be stored for 15 years. In the informed consent parents can indicate if they can be approached for future research questions with the data.

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 patients will recieve a unique studynumber. The site (hospital where the patient is included) will have access to a confidential list with names and birth dates of the patients.

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 an online (metadata) catalogue or web portal (please specify)

Metadata is available via DANS EASY and DOI code.

https://doi.org/10.17026/dans-zkf-b9vq

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 platform

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

https://doi.org/10.17026/dans-zkf-b9vq

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 made accessible to public after publication of the results both in primary outcome as in secundary outcomes including center specific goals.

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)

Currently the informed consent file gives permission to use the data for the goals specified in the patient information folder.
Although parents could indicate that they could be approached for follow up research. Currently all data is pseudo-anonymized.
Access can only be given for anonymized data. The primary research group will monitor and facilitate data access.
|IN accordance with the ErasmusMC policy and RESEARCH suite po0licy and legal advice anonymized data will be made available on request

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 are currently working with our legal administrators to set up terms of use.

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

- The reimbursement of costs, for example in obtaining the data
- The permitted period of use of the data set
- The manner in which the data set can be accessed
- Whether or not the data set may be linked with another data set (for reasons of privacy)
- 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
- Conditions related to data security

The final terms will be made in conjunction with our legal department.

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)

We are currently transfering our data to CASTOR as a data management system to facilitate data extraction.

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)
ICD-10 codes (disease classification)

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 software used in the course of the project (please specify)
- In addition, I will take further quality assurance measures (please specify)
- 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)

All steps of the study have been documented.
A 100% data monitoring has been done to safeguard data quality by both researchers and a dedicated research nurse in all participating centers.
A DSMB has been reviewing the study during inclusion safeguarding primary outcomes and safety.
Data is stored in open clinica ecrf.
SPSS has been used for statistical analysis.

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.

- Not yet (please explain)

Data is currently processed and saved on our institutions servers.

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)

- Not yet

This will be done within the erasmusMC according the institutions guidelines

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)

15 years

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 costs of the data management has been funded. Data is currently stored on ErasmusMc servers and financed in kind by the department. Data managers are financed in kind by the department.

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

- Not yet (please explain)

archiving data costs will be covered by the department of Pediatric an Neonatal Intensive Care.