

Plan Overview

A Data Management Plan created using DMPTool

Title: Mean arterial pressure reduction during the first ten minutes after general anesthesia induction using propofol bolus or triated target-infusion: superiority randomized controlled trial.

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Project abstract:

This study will test the hypothesis that the incidence of significant hypotension during the first 10 minutes, defined as drop in mean arterial pressure of 20% or more, is greater when using a general anesthesia induction using 2mg/kg of propofol followed by 2% of sevoflurane when compared to a general anesthesia using target-controlled infusion (Marsh model) followed by a 30% increase in target levels.

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Mean arterial pressure reduction during the first ten minutes after general anesthesia induction using propofol bolus or triated target-infusion: superiority randomized controlled trial.

Data Collection

What data will you collect or create?

We expect to collect data from 120 patients using google forms and exporting to a XLSX format. Data will also be exported to CSV for long-term access.

How will the data be collected or created?

All data will be collected using structured google forms, which will handle versioning and folder.

The study data scientist will check for consistency by verifying the range of numerical values (age must be included in 18-60 interval, MAP must be between 20 and 200mmHg, HR must be between 20 and 200, BIS must be between 0 and 100 and SR must be between 0 and 100).

Documentation and Metadata

What documentation and metadata will accompany the data?

A readme file will be published with the individual patient data, containing variables names and description.

Our data scientist will write the readme file and describe the study methodology. An RPubs link with a statistical analysis plan will be informed.

Ethics and Legal Compliance

How will you manage any ethical issues?

We predicted and informed about individual patient data sharing to the ethics comitee and we discuss about it with our voluntary patients. To protect all patients, the only way to identify an individual patient's data is by looking for his specific ID code printed in the informed consent. The ID code is mantained for posterior data withdraw purposes before IPD publication. No sensitive data will be stored.

How will you manage copyright and Intellectual Property Rights (IP/IPR) issues?

Research team will own the data until it is published. We plan to publish under CC BY 4.0.

Storage and Backup

How will the data be stored and backed up during the research?

During the research, data will be backed up in paper forms and google forms by the data scientist. After it is published by Mendeley Data, paper backup will be destroyed.

How will you manage access and security?

No sensitive data will be collected and all data collected will be anonymized. Only data we intend to publish will be collected.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

Data may be reused for sample size calculations, prior probabilities for future studies, systematic meta-analysis of IPD or any other health-related science improvement. All the data will be kept for as long as Mendeley data can. In case of Mendeley Data failure, we plan to share it again in another server.

What is the long-term preservation plan for the dataset?

Mendeley Data, free repository.

Data Sharing

How will you share the data?

In Mendeley Data

Are any restrictions on data sharing required?

CC BY 4.0

Responsibilities and Resources

Who will be responsible for data management?

The study data scientist. Data will be open.

What resources will you require to deliver your plan?

No additional resource.
