Analytical Plan for Study design for the association between peak troponin levels and post-surgery mortality in an Australian hospital

DOCUMENT: SAP-2022-019-v01

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2022-04-11

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Analytical Plan for Study design for the association between peak troponin levels and post-surgery mortality in an Australian hospital

**Document version**

|  |  |
| --- | --- |
| **Version** | **Alterations** |
| 01 | Initial version |

# Abbreviations

* CI: confidence interval
* HR: hazards ratio
* ICU: Intensive care unit
* SD: standard deviation

# Context

## Objectives

Study design for the association between peak troponin measurements and in hospital mortality adjusting for scores on EURO scores and APACHE.

## Hypotheses

## Study design

Prospective cohort.

# Data

## Raw data

The original data base had 8 variables collected on 200 observations.

## Analytical dataset

All variables in the analytical set were labeled according to the raw data provided and values were labeled according to the data dictionary for the preparation of production-quality results tables and figures.

After the cleaning process 8 variables were included in the analysis. The total number of observations excluded due to incompleteness and exclusion criteria will be reported in the analysis. Table 1 shows the structure of the analytical dataset.

**Table 1** Analytical dataset structure after variable selection and cleaning.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **id** | **outcome** | **troponin** | **euroscore** | **apache** | **surg\_type** | **surg\_length** | **icu\_length** |
| 1 |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |
| … |  |  |  |  |  |  |  |
| 200 |  |  |  |  |  |  |  |

# Study parameters

## Inclusion and exclusion criteria

## Exposures

Peak troponin levels, measured as a continuous scale.

## Outcomes

**Specification of outcome measures** (Zarin, 2011):

1. (Domain) Mortality
2. (Specific measurement) In hospital death counts
3. (Specific metric) Time to event
4. (Method of aggregation) Hazards ratio

**Primary outcome**

## Covariates

Hazard ratios will be adjusted for Euro score, APACHE score, type of surgery, length of surgery and length of ICU stay.

# Statistical methods

## Statistical analyses

### Descriptive analyses

The epidemiological profile of the study participants will be described. Demographic (sex, age and BMI) and clinical variables ( EURO score, APACHE score, type of surgery, length of surgery and length of ICU stay ) will be described as mean (SD) or as counts and proportions (%), as appropriate. The distributions of participants’ characteristics will be summarized in tables and visualized in exploratory plots.

### Inferential analyses

### Statistical modeling

### Missing data

No missing data imputation will be performed. All evaluations will be performed as complete case analyses.

## Significance and Confidence Intervals

All analyses will be performed using the significance level of 5%. All significance hypothesis tests and confidence intervals computed will be two-tailed.

## Study size and Power

The study protocol defines an intended sample size of 200 patients.

## Statistical packages

This analysis will be performed using statistical software R version 4.1.3.

# Observations and limitations

# References

* **SAR-2022-019-v01** – Study design for the association between peak troponin levels and post-surgery mortality in an Australian hospital
* Zarin DA, et al. The ClinicalTrials.gov results database – update and key issues. N Engl J Med 2011;364:852-60 (<https://doi.org/10.1056/NEJMsa1012065>).
* Gamble C, et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA. 2017;318(23):2337–2343 (<https://doi.org/10.1001/jama.2017.18556>).

# Appendix

This document was elaborated following recommendations on the structure for Statistical Analysis Plans (Gamble, 2017) for better transparency and clarity.

## Availability

All documents from this consultation were included in the consultant’s Portfolio.

The portfolio is available at:

<https://philsf-biostat.github.io/SAR-2022-019/>