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

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Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

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

2 CONTEXT

2.1 Objectives

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

2.2 Hypotheses

2.3 Study design

Prospective cohort.

3 DATA

3.1 Raw data

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

3.2 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							

4 STUDY PARAMETERS

4.1 Inclusion and exclusion criteria

4.2 Exposures

Peak troponin levels, measured as a continuous scale.

4.3 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

4.4 Covariates

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

5 STATISTICAL METHODS

5.1 Statistical analyses

5.1.1 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.

5.1.2 Inferential analyses

5.1.3 Statistical modeling

5.1.4 Missing data

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

5.2 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.

5.3 Study size and Power

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

5.4 Statistical packages

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

6 OBSERVATIONS AND LIMITATIONS

7 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).

8 APPENDIX

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

8.1 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/