

19th September, 2022

TAME Cardiac Arrest trial SAP Update

The following should be read in conjunction with the published protocol and statistical analysis plan (SAP) for the TAME Cardiac Arrest trial¹ and the SAP update letter dated 7th September 2022. All amendments to the manuscript, supplemental appendix and planned analyses were made prior to access of any unblinded data. This update was necessary as limitations with data presentation as identified in the TAME protocol and SAP and the Appendix to the TAME Protocol and SAP were identified.

Manuscript – TAME Protocol and SAP – V5

#1 – *Manuscript section titled ‘Statistical analysis plan’*

Change in wording

- Change from ‘Risk ratios’ to ‘Risk differences’ in the third sentence, paragraph two. So that is now reads: “Risk differences and 95% confidence interval will be assessed with the use of a mixed-effects generalized linear model with a logit link, centre as random intercept, and with co-enrolment included as fixed effect.”

Rationale: Risk difference is applicable in this instance as we our primary outcome is composite outcome (favourable versus unfavourable GOSE) and not a binary outcome (e.g. 180-survival).

SAP Supplemental Appendix – V5

#2 – *Table 2*

Column clarification for the use of ‘Risk Difference (95% CI) in table 2

- Amendments made to the layout of the column associated with the presentation of Risk Difference and 95% confidence interval reporting.



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References

1. Holmberg MJ, Anderson LW. Estimating Risk Ratios and Risk Differences: Alternative to Odds Ratios. *JAMA*.2020; 324(11):1098-1099. doi: 10.1001/jama.2020.12698