

7th 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 25th August 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 – V4

#1 – Table 2. *Physiological descriptors and process of care measures*

Deletion of reference to the collection of ‘Thrombolysis’ data

- Thrombolysis data not collected in the TAME case report form and as such is unable to be presented.

Change in wording regarding targeted temperature management

- Data collected via case report form regarding temperature management described as ‘Device used for targeted temperature management’ and replaces the wording ‘targeted therapeutic hypothermia.’

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#2 – Table 3. *Data to be collected in the TAME trial*

Deletion of reference to the collection of ‘Mode of ventilation used most frequently while ventilated

- Mode of ventilation used during mechanical ventilation was data not collected in the TAME case report form and as such is unable to be presented.

SAP Supplemental Appendix – V4

#3 – Table S2

In the section titled: Intervention during ICU admission, no.%

- Variable title changed from ‘Targeted therapeutic hypothermia’ changed to ‘Device used for target temperature management’
- Thrombolysis data variable removed

Glenn Eastwood

Chief Principal Investigator
On behalf of the TAME Management Committee
TAME Cardiac Arrest
T: + 61 3 9496 4835
E: glenn.eastwood@monash.edu

Trial registration:

ClinicalTrials.gov: NCT03114033; and,
Australian and New Zealand Clinical Trials Registry: ACTRN12617000036314p

References

1. Nichol A, Bellomo R, Ady B, et al. Protocol summary and statistical analysis plan for the Targeted Therapeutic Mild Hypercapnia after Resuscitated Cardiac Arrest (TAME) trial. *Crit Care Resusc* 2021;23(4):374-385. <https://doi.org/10/51893/2021.4.OA2>