TITLE (SHORT, 200 CHARACTERS MAX.):

A POST-HOC ANALYSIS TO DETERMINE PARAMETERS THAT PREDICT 100% MORTALITY FOLLOWING OUT-OF-HOSPITAL CARDIAC ARREST IN AUSTRALIA AND NEW ZEALAND

MAIN HYPOTHESES TESTED (2 MAX)

Following out-of-hospital cardiac arrest (OHCA), in Australia or New Zealand, there are clinical and investigation parameters present at 24 hours that portend 100% mortality at 90 days.

SINGLE CENTER [ ] , MULTICENTER [X]

All Australian and New Zealand sites participating in TTM2 and the TAME trials.

PICO

Patients: All Australian and New Zealand sites participating in TTM2 and the TAME trials.

Intervention/Exposure/Prognostic factor: Nil intervention

DATA NEEDED FOR THE ANALYSIS (SPECIFY VARIABLES AND MOTIVATE ANY PROPOSED ADDITIONS TO THE ECRF)

All potential clinical risk factors and investigations that may be predictive of mortality after cardiac arrest (such as age, witnessed versus unwitnessed arrest, bystander CPR versus no bystander CPR, initial electrocardiographic rhythm, etc.), that are being routinely collected already for the TTM2 study on the ECRF. We currently propose no additions to the ECRF.

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

Data is already being collected as a routine for the study on the ECRF.

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

The study is a pre-planned post-hoc analysis of the TTM2 study dataset. It will be an observational derivation study.

We plan to determine from the existing TTM2 dataset which potential risk factors when combined together may predict 100% mortality in patients who have an OHCA in Australia and New Zealand.

Australian and New Zealand patients would be analyzed separately, due to differences in health care provision in both countries. The sample size in Australia is expected to be larger than the sample size in New Zealand.

Assuming a sample size of 300 patients in Australia, if the observed mortality rate was 0.99, the lower limit for the 95% confidence interval would be 0.97, using the Clopper-Pearson Exact formula. However, we expect a significantly lower number of patients to have risk factors that portend a predicted mortality of 0.99. Accordingly, the lower limit for the 95% confidence interval will be considerably less than 0.97. Because of this and because the study is a derivation study, the study results will only generate a hypothesis, on which factors may predict 100% mortality following OHCA. These results will need to be validated in a future validation study.

Multiple regression will be used to test independent variables. A sample size of 300 patients will detect the minimum detectable R-squared value, assuming 7 independent variables are used. This sample size will achieve 80%

power to detect an R-squared of 0.05 attributed to 7 independent variables using an F-Test with a significance level of 0.05.

FUNDING (IF APPLICBABLE)

None currently

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