

A Prospective Randomised Trial of Early LV Venting Using Impella CP for Recovery in patients with cardiogenic shock managed with VA ECMO (REVERSE)

REVERSE Trial

Statistical analysis plan

Date Dec 20 2017

NCT Yet to be assigned

The primary endpoint in the data analysis is binary: 45-day survival free from mechanical circulatory support, heart transplantation, or inotropes. The null hypothesis of no difference between VA (VA ECMO) and VA+I (VA ECMO plus Impella) will be tested using logistic regression, with a binary indicator for treatment arm and adjustment as necessary for potential confounding variables not included in the design. The secondary endpoint, survival to discharge, will be addressed using competing risks hazard regression models, with discharge and hospital mortality as competing events and adjustment as necessary for confounding variables not included in the design. For both primary and secondary analyses, assumptions of linear covariate effects will be examined using cubic splines. In the hazard rate regression models potential time-dependence of the hazard ratio will be examined using restricted cubic spline methodology. Finally, group differences in inotropic scores and other continuous measures will be tested by ANOVA, whereas group effects on categorical outcomes will be tested by contingency tables. Assumptions of normally distributed outcomes in ANOVA will be relaxed as necessary by employing Kruskal-Wallis nonparametric ANOVA. Multiple testing will be addressed where appropriate by computing resampling-based adjusted P-values.