# STEPCARE sub-study proposal

### Title (short, 200 characters max.):

### Short-Term Mechanical Circulatory Support After Cardiac Arrest: Observational Analysis of IABP, ECMO, and Impella in the STEPCARE Trial Population

### Main hypothesEs tested (2 max)

### Cardiac arrest survivors frequently develop post-resuscitation shock and myocardial dysfunction, with high early mortality. Short-term mechanical circulatory support (MCS) devices—including intra-aortic balloon pump (IABP), veno-arterial extracorporeal membrane oxygenation (VA-ECMO), and percutaneous microaxial pumps (Impella)—are increasingly used to support circulatory failure.

### While ECMO and Impella have shown promise in selected patients, robust comparative data are lacking, especially in mixed populations of out-of-hospital cardiac arrest (OHCA). Additionally, clinical profiles associated with benefit from these devices remain poorly defined.

### The STEPCARE trial provides a unique opportunity to analyze the real-world use and outcomes of MCS across multiple centers.

Main hypothesis: The use of short-term mechanical circulatory support (MCS) after cardiac arrest is associated with improved 180-day survival and favorable neurological outcomes in a selected subgroup of patients with cardiac arrest. The benefit of MCS differs by device type (IABP, ECMO, Impella), initial rhythm, timing of use.

### Single Center [ ] , Multicenter [X]

All STEPCARE participating centers

### PICO

Patient: All patients enrolled in STEPCARE with sustained ROSC after OHCA and evidence of post-resuscitation severe shock (SCAI C, D, E)

Intervention/Exposure/Prognostic factor: Use of short-term MCS: IABP, ECMO (post-ROSC), or Impella during index hospitalization

Comparison: Patients with post-resuscitation cardiogenic shock SCAI C, D, E managed without MCS devices (standard care including vasopressors/inotropes alone)

Outcome: 180d survival, 180d neurological outcome (mRS), safety endpoints during hospitalization

### Data needed for the analysis (Specify variables and motivate any proposed additions to the eCRF)

Baseline characteristics – all available

Outcomes – 30d, 180d mortality and mRS

Safety outcomes

### Logistics – How will additional data be gathered?

There are no additional data needed, all data are part of the STEPCARE database

### Brief statistical analysis plan and sample size estimate

Baseline characteristics (demographics, comorbidities, initial rhythm, location of arrest) across:

MCS vs. non-MCS groups

Device-specific subgroups (IABP, ECMO, Impella)

Use means (±SD) or medians (IQR) for continuous variables; counts (%) for categorical.

Primary Analysis

Unadjusted outcome comparison:

180-day mortality using Kaplan–Meier survival curves, log-rank test

mRS good or poor outcome (Chi-squared test)

Multivariable Cox regression for 180-day mortality and neurological outcome including covariates:

Age, sex, arrest location (public versus home), initial rhythm, time to ROSC, and use of MCS (yes/no; device-specific).

Propensity score matching or inverse probability of treatment weighting (IPTW) to adjust for treatment selection bias.

Subgroup Analyses

Stratify by: initial rhythm (shockable vs. non-shockable), time from arrest to MCS initiation, device type (IABP vs. ECMO vs. Impella), shock severity (SCAI C, D, E).

Sample Size Considerations

As an observational substudy of a larger trial, power will depend on actual rates of MCS use across sites. Assuming ~10-15% MCS utilization within STEPCARE (~300–400 patients), and 2:1 control-to-exposure ratio, the study should have sufficient power to detect meaningful differences (>10% absolute) in survival.

Conclusion

The STEP-MCS substudy aims to clarify the role and impact of short-term mechanical circulatory support in post-cardiac arrest patients. The analysis will define clinical profiles most likely to benefit from MCS.

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NA

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