TITLE (SHORT, 200 CHARACTERS MAX.):

THE IMPACT OF BLOOD PRESSURE TARGETS IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION AND SHOCK FOLLOWING OHCA

MAIN HYPOTHESES TESTED (2 MAX)

The aim of this sub-study is to better understand the influence of blood pressure targets in patients with acute myocardial infarction (AMI) and shock following out of hospital cardiac arrest (OHCA).

Ameloot and colleagues conducted an analysis of a cohort of patients with AMI and shock following OHCA included in the COMACARE and NEUROPROTECT trials.[1] Those randomized to higher MAP targets had a lower area under the 72-h high-sensitivity troponin-T (hs-TnT) curve than those randomized to lower MAP targets. Between group differences were driven primarily by lower hs-TnT in those with ST-elevation myocardial infarction (STEMI) and those where the culprit lesion was left anterior descending (LAD) / left mainstem (LM) coronary arteries.

We hypothesise that:

In patients with AMI and shock following OHCA, those randomized to MAP 85mmHg will have better outcomes than those randomized to 65mmHg.

SINGLE CENTER [ ], MULTICENTER [X]

Analysis of entire STEP-CARE database.

PICO

Patients:

Patients with AMI and shock on admission included in the STEP-CARE trial.

Shock on admission will be defined as systolic blood pressure <90mmHg for at least 30 minutes or the need for supportive measure to maintain a systolic blood pressure ≥90mmHg and end-organ hypoperfusion (cool extremities, or urine output of less than 30ml/hr, and a HR >60 beats per minute)

Patient with AMI will be identified based on presumed cause of cardiac arrest recorded in eCRF as follows:

- Cardiac – ST-elevation myocardial infarction / acute coronary occlusion
- Cardiac – non-ST elevation myocardial infarction

Subgroup analysis will be conducted looking at the differential effects for the following groups:

- STEMI versus NSTEMI
- LAD/LM culprit lesion versus not LAD/LM culprit lesion
- SCAI criteria beginning / classic / deteriorating / extremous
- Pre-existing hypertension versus no pre-existing hypertension

Intervention/Exposure/Prognostic factor:

MAP 85mmHg

Comparison:

MAP 65mmHg

Outcome:

Primary Outcome measure:

Mortality at 96 hours. This outcome measure was chosen to identify early mortality due to cardiogenic shock / multi-organ failure (deaths beyond 96 hours will be predominantly neurological)

Secondary Outcome measures:

1. AUC lactate (recorded at 0,12, 24, 48 and 72 hours in STEP-CARE eCRF) as a marker of shock resolution
2. Levels of cardiovascular support
    - Mean noradrenaline dose in first 72 hours (noradrenaline dose recorded at 0, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 48 and 72).
    - Use of dobutamine, adrenaline, milrinone, vasopressin and levosimendan in first 72h
3. Rates of arrhythmia or cardiac arrest requiring defibrillation/cardioversion or chest compressions
4. Use of Impella / ECMO / IABP
5. Rates of "MAP-target changed or abandoned before extubation or 72h"
6. Hs-Tnt if available
7. NT-proBNP if available
8. Rates of renal replacement therapy
9. Mortality at 6 months
10. Neurological outcome at 6 months
11. EQ5D-5L at 6 months

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

Nil additional. All relevant data will be captured in the current eCRF.

Analysis will include hs-TnT and NT-proBNP where captured in the eCRF or subsequent biobank study.

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

In current eCRF.

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

A detailed Statistical Analysis Plan will be written, agreed with a statistician and made openly available prior to undertaking analysis. Baseline characteristics, follow-up measurements and safety data will be described using the appropriate descriptive summary measures as per the STEP-CARE protocol.

FUNDING (IF APPLICBABLE)

Not applicable.

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References

1. Ameloot K, Jakkula P, Hästbacka J, Reinikainen M, Pettilä V, Loisa P, et al. Optimum Blood Pressure in Patients With Shock After Acute Myocardial Infarction and Cardiac Arrest. J Am Coll Cardiol. 2020 Aug 18;76(7):812–24.