TITLE (SHORT, 200 CHARACTERS MAX.):

CAN TROPONIN LEVELS IDENTIFY ACUTE CORONARY SYNDROME IN POST CARDIAC ARREST PATIENTS?

MAIN HYPOTHESES TESTED (2 MAX)

Nearly all patients with cardiac arrest have increased troponins, complicating its clinical interpretation. Can high-sensitivity troponin T (hsTnT) or troponin I identify post cardiac arrest patients who would suffer from acute coronary syndromes and could benefit from coronary angiography?

SINGLE CENTER [ ] , MULTICENTER [X]

Sahlgrenska university hospital, Gothenburg Sweden

Preferably the whole STEP CARE population.

PICO

Patients: Patients included in STEP-CARE with at least one measurement of troponin (hsTnT or TNI) and coronary angiography performed during the hospital stay.

Intervention/Exposure/Prognostic factor: Absolute levels of troponinsand relative change in troponins until 72 hours after randomization

Comparison: Three groups: Patients with normal coronary angiography (group 1), patients with chronic coronary disease and no PCI (group 2) and patients with acute coronary/culprit lesions and/or PCI (group 3).

Outcome: Prognostic performance of hsTnT to identify patients with an acute coronary lesion and/or PCI (group 3)

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

Data of troponin measurements during 72 hours after randomization. To evaluate the prognostic performance of initial troponin, maximum value and dynamic changes of troponin, the eCRF should permit imputation of multiple input of troponins.

Data on whether coronary angiography was performed and preferably the findings of the angiography.

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

Troponin measurements and the decision to perform coronary angiography is done at the discretion of the treating clinicians. Data is ~~imputed~~ irecorded in the eCRF when available.

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

To make a clinically relevant study, we expect that at least 100 patients are needed in each group. This to achieve acceptable ROC curves and discrimination between the groups. Data from our institution suggests that group 3 is roughly three times the size of group 1 and group 2. This would result in a total sample size of 500 patients (group 1:

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100 patients, group 2: 100 patients and group 3: 300 patients). ROC curves will be used to find best cut off (Youden test), as well as cut-off values for e.g., 95% sensitivity of having an acute coronary lesion.

FUNDING (IF APPLICBABLE)

If the sub-study is accepted, grant applications will be written to the Swedish Heart and Lung foundation, Gothenburg Society of Medicine, Swedish Society of Medicine and the Emelle foundation. Local coststs for data compilation, statistical analyses, article writing etc. are covered by the clinic and other grants (e.g., ALF funding).

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