

TITLE (SHORT, 200 CHARACTERS MAX.):

# THE EFFECT OF HIGH VERSUS LOW MEAN ARTERIAL PRESSURE ON LEFT VENTRICULAR DYSFUNCTION IN POST CARDIAC ARREST PATIENTS

MAIN HYPOTHESES TESTED (2 MAX)

Higher mean arterial pressure will improve cardiac function, and decrease troponin release, by increasing coronary perfusion and oxygen delivery to cardiac tissue in comatose patients after cardiac arrest

SINGLE CENTER [ ] , MULTICENTER [ ]

Sahlgrenska university hospital

Sites interested in performing serial echocardiographic evaluations in patients included in the STEP-CARE trial.

PICO

Patients:

Patients included in the STEP-CARE trial at sites having an ejection fraction of 40% or less at the first echocardiographic evaluation and a repeated echocardiographic examination within 72 hours

Intervention/Exposure/Prognostic factor: High versus low MAP

Comparison: Patients randomized to high versus patients randomized to low MAP during the initial 72 hours. Two separate groups will be analyzed, those with and those without acute coronary syndromes.

Outcome: Primary outcome is improvement in ejection fraction during first 72 hours after randomization. Secondary outcomes are improvement in regional wall motion abnormalities, proportion of patients normalizing left ventricular function and troponin levels during first 72 hours after randomization.

DATA NEEDED FOR THE ANALYSIS

(SPECIFY VARIABLES AND MOTIVATE ANY PROPOSED ADDITIONS TO THE ECRF)

Echocardiographic evaluations will take place within 12 hours after randomization and then repeated at within 72 hours after randomization

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

Echocardiographic data will be collected from participating sites after the main study has been published. Echocardiographic data will be reviewed by an expert in echocardiography blinded to patient group allocation.

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

Expecting an increase in ejection fraction of  $5 \pm 2.5\%$  in the high MAP group per 12 hours (i.e., 20% over 48 hours) and an increase in ejection fraction of  $3.75 \pm 2.5\%$  in the low map group per 12 hours (i.e., 15% over 48 hours), the sample size would be 63 patients in each group. Due to a presumed non-parametric distribution of data, 20% is Please send this form as a pdf to [josef.dankiewicz@gmail.com](mailto:josef.dankiewicz@gmail.com)

added to the sample size thus aiming at a total of 75 patients in each group. Analysis will be performed for separately for patients with vs. without acute coronary syndromes, generating four groups in total. Improvement in ejection fraction over time between the groups will be analyzed with a linear mixed model. The model will take time to second echo in consideration.

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#### FUNDING (IF APPLICABLE)

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 and included in future ALF applications. Local costs for data compilation, statistical analyses, article writing etc. are covered by the clinic and other grants (e.g., ALF funding).

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#### CO-WORKERS: