

TITLE (SHORT, 200 CHARACTERS MAX.):

## EARLY POST-ROSC COOLING IN CARDIAC ARREST

MAIN HYPOTHESES TESTED (2 MAX)

Early onset of cooling with trans-nasal evaporative cooling (RhinoChill) with the aim to primarily cool the brain will reduce the time to reach target temperature ( $\leq 33^{\circ}\text{C}$ ) and improve neurological outcome.

SINGLE CENTER [ ] , MULTICENTER [X ]

Karolinska Institutet, Stockholm. Erasme, Brussels, Charles University, Prague.

PICO

Patients: Patients randomized to hypothermia in participating sites

Intervention/Exposure/Prognostic factor: Trans-nasal cooling (RhinoChill) started in the Emergency room.

Comparison: (1) Patients randomized to hypothermia where cooling is started at ICU and (2) patient randomized to control group. Patients in the comparison groups will be matched with intervention using propensity score.

Outcome: Time to target temperature. Complete neurological recovery, defined as Glasgow Outcome Scale Extended (GOSE) 8, in a scale from 1-8. Safety.

DATA NEEDED FOR THE ANALYSIS

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

No specific variables will be collected besides device related adverse events.

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

The participating sites will record device related adverse event in a separate CRF.

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

The aim is to include at least 50 patients in the “early cooling” treatment arm. These will be matched with propensity score 1:1:1 with patient in the control group and in the “late cooling” group.

Primary outcome will be time to target temperature compared to cooling initiated at ICU.

FUNDING (IF APPLICABLE)

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