

TITLE (SHORT, 200 CHARACTERS MAX.):

IMPACT OF SEDATION ON NEUROLOGICAL AND COGNITIVE FUNCTION AFTER CARDIAC ARREST: A SUBANALYSIS OF TTM2

MAIN HYPOTHESES TESTED (2 MAX)

The aim of this sub-study is to describe and compare how anaesthetic medication such as sedative and analgesia given during ICU care affect the patients in terms of neurological and cognitive function at one and six months after cardiac arrest.

SINGLE CENTER [] , MULTICENTER [X]

Multicenter trial with all TTM2 sites willing to participate

PICO

Patients: All patients admitted in ICU after OHCA included in TTM2 Trial. Patients dying before 1 month are excluded

Intervention/Exposure/Prognostic factor: None

Comparison: Compare drugs and doses of sedative and analgesia.

Outcome: Neurological and cognitive function 6 month after cardiac arrest

DATA NEEDED FOR THE ANALYSIS

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

Neurological and cognitive function at 1 and 6 month

Sedation dose, type, length

Analgesia dose, type, length

Temperature

Body weight, length

RASS score

Baseline data from the cardiac arrest, also including co-morbidity and socio-demographic data

Hemodynamic data including use of vasopressor

Use of neuromuscular blocker

Time on mechanical ventilation

Time on CRRT

Please send this form as a pdf to ttm2@ttm2trial.org

Length of ICU and hospital stay

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

Information related to medical history and the cardiac arrest as described in the TTM2 protocol.

No additional data needed if the above is included in the ECRF.

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

Statistical analysis with ANOVA, non-parametric test and multiple regression analysis

FUNDING (IF APPLICABLE)

Institutional grants. Grants will be applied from other sources of funding.

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Other co-workers from participating sites can be included.