TITLE (SHORT, 200 CHARACTERS MAX.):

SERUM CONCENTRATIONS OF SEDATIVE DRUGS

MAIN HYPOTHESES TESTED (2 MAX)

Level of TTM affects serum concentrations of sedative drugs

SINGLE CENTER [X] , MULTICENTER [X]

All sites: eCRF data (below).

Helsingborg Hospital (all Region Skåne sites and Halmstad if funding permits): serum concentrations of sedative drugs at end-of-intervention (40 hours) and at 96 hours after cardiac arrest (patients still in coma).

PICO

Patients: 100 patients

Intervention/Exposure/Prognostic factor: sedation

Comparison: TTM33 vs fever control

Outcome: concentrations of sedative drugs

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

Serum concentrations of sedatives, analgesics and antiepileptics. Number of sedatives will be limited in the Region Skåne Protocol.

eCRF: Total doses of sedatives at end of intervention and at 96 hours after cardiac arrest. Time sedation stopped. Time of awakening.

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

Blood samples will be collected by nursing staff and sent to hospital lab services for centrifugation, freezing. Analysis will be performed at Rättsmedicinalverket, University of Lindköping, Sweden.

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

Serum concentrations will be a descriptive study.

FUNDING (IF APPLICBABLE)

SEK 1350 per patient (this incudes serum analysis of: propofol, midazolam, fentanyl, ketamine, ketobemidon, morphine, clonidine, dexmetomidon). Cost of serum levels of antiepileptics on hospital's budget. Applying for additional funding via Helsingborg Hospital.

CORRESPONDING AUTHORS NAME, INSTITUTION & E-MAIL ADDRESS:

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

Anna Lybeck, Lund University, anna.lybeck@med.lu.se

CO-WORKERS:

Martin Annborn, Hans Friberg, Tobias Cronberg, Niklas Nielsen, Josef Dankiewicz