TITLE (SHORT, 200 CHARACTERS MAX.):

DYSGLYCAEMIA, GLYCAEMIC VARIABILITY AND COGNITIVE OUTCOME AFTER CARDIAC ARREST AND TEMPERATURE MANAGEMENT AT 33 °C VS NORMOTHERMIA

MAIN HYPOTHESES TESTED (2 MAX)

(1) Hypoglycemia, higher mean glucose/insulin dose/glucose variability are associated with a worse cognitive outcome after cardiac arrest.
(2) A target temperature of 33 °C is associated with higher mean glucose, insulin dose and glucose variability compared to normothermia.

SINGLE CENTER [ ] , MULTICENTER [X]

Data from all TTM centers (as per protocol). If possible, more (pre-specified) data points (blood glucose levels) from Lund, Helsingborg, Malmö, Cardiff, Leeuwarden.

PICO

Patients: All patients included in the TTM2 trial.

Intervention/Exposure/Prognostic factor: insulin use/insulin dose/dysglycaemia/glycaemic variability.

Comparison: hyper-/hypoglycaemia vs normoglycaemia, glycaemic variability

Outcome: mRS/CPC/SDMT.

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

HbA1c level at admission and at follow-up.

Diabetes status – type 1 vs type 2.

If possible, frequent (8/day?) blood glucose measurements during the intervention period (mainly first 48 hours, expected to be easier to control the glucose levels thereafter).

Total daily insulin dose.

TPN/EN/glucose infusions.

Steroids.

Daily: hypo- or hyperglycemia (<4 mmol/l and >10 mmol/l, respectively)?

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

Additional data (blood glucose levels), if possible, will be collected from member sites.

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

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

As in a previous, similar post hoc study using TTM1 data, non-parametric tests as well as multiple logistic regression and mixed effects logistic regression models will be used. Median, range and mean absolute glucose (MAG) will be used when analyzing glycaemic variability.

Sample size would ideally be as large as possible in order to analyze data on hypoglycemia (which had a low incidence in the TTM1 trial).

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