

TITLE (SHORT, 200 CHARACTERS MAX.):

BRAIN COMPUTED TOMOGRAPHY TO PREDICT OUTCOME AFTER CARDIAC ARREST

MAIN HYPOTHESES TESTED (2 MAX)

Results from the TTM-trial and other studies indicate that CT is a valuable and commonly used tool to predict neurological outcome after cardiac arrest and that the sensitivity may increase if the examination is delayed. However, previous studies are hampered by selection bias. In addition automated measurement of gray-white matter ratios may increase the predictive value and interrater reliability compared to standard visual evaluation..

Hypotheses:

- Gray white matter ratio (GWR, calculated with a rater independent algorithm) and visual evaluation of generalized edema of brain computed tomography predicts poor outcome after cardiac arrest
- The sensitivity, specificity and interrater reliability of poor outcome prediction by CT is higher using automated measurement of GWR compared to visual evaluation.

SINGLE CENTER [], MULTICENTER [X]

All centers performing CT for prognostication of outcome are welcome to participate

PICO

Patients: all patients included in TTM2 at the participating sites and who are still unconscious 48 hours after cardiac arrest.

Intervention/Exposure/Prognostic factor: Automated GWR measure and standard eye balling of brain CT.

Comparison: sensitivity, specificity and interrater variability using automated measurement compared to standard visual evaluation by blinded radiologist and with the local unblinded CT examination performed as a part of the routine care.

Outcome: GOSE and mRS at 6 months

DATA NEEDED FOR THE ANALYSIS

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

Original brain CT scan data, outcome and baseline (age, sex, initial rhythm etc.) data, NSE-levels. Results of the local CT interpretation performed during the trial and entered into the eCRF as: Generalized edema YES/NO.

No modification of eCRF necessary.

LOGISTICS – HOW WILL ADDITIONAL DATA BE GATHERED?

The brain CT data will be retrieved to a central database. Original brain CT scan data will be anonymized and sent via data sharing platform. Radiology experts blinded to clinical data will evaluate all scans centrally after completion of the TTM2 trial. Automated GWR measurements will also be performed in a blinded fashion by independent examiners.

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

BRIEF STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE ESTIMATE

Determination of lower threshold of GWR (calculated by a computer algorithm, independent of a human rater) to predict poor outcome, specificities, sensitivities, positive predictive value, false positive rate with 95% confidence intervals. ROC-analyses to find optimal cut-off values for GWR. Sample size: all CT available in order to keep 95% CI as low as possible.

FUNDING (IF APPLICABLE)

The CT examination will be used for neurological prognostication and considered as standard care in the participating centers. No reimbursement will be provided. All centers contributing > 30 patients will be offered participation in the analyses and publication of the results.

CORRESPONDING AUTHORS NAME, INSTITUTION & E-MAIL ADDRESS/CO-WORKERS:

MARION MOSEBY, DPT OF NEUROLOGY, LUND, SWEDEN. MARION.MOSEBY@MED.LU.SE

CHRISTOPH LEITHNER, TOBIAS CRONBERG, CHRISTIAN STORM, CHRISTIAN RYLANDER