Neurology FAQ Ethics/Timing/Personnel/Neurophysiology/Help

Ethics

- Why should we wait to perform neuroprognostication until 96 hrs in a patient with signs of a severe brain injury such as global edema on brain CT and lack of pupillary reflexes?

  There are no 100% accurate methods to prognosticate and the evidence supporting various combinations is very limited. The 96 hrs observation period should be regarded as a minimum to allow for recovery of consciousness after weaning of sedation in case the other methods prove wrong.

- How should we act if we feel that it is unethical to prolong care until 96 hrs in order to neuroprognosticate a patient with for example, terminal illness, multi-organ failure or an expressed wish not to be resuscitated?

  You may withdraw life-sustaining therapy in such a patient prior to 96 hrs for ethical reasons according to protocol. Report all your reasons in the WLST-form of the eCRF. A perceived severe brain injury may be a part of your reasons but never the sole reason for withdrawal of care since a definitive judgement cannot be made before 96 hrs. Describe neurological findings as "other reasons", box E.

Timing

- Are there any situations where it is according to protocol to perform the neuroprognostication before 96 hrs after randomization?

  No. Please report as a protocol deviation if it still happens.

- We accidentally performed neuroprognostication at 90 hrs, what should we do.

  If you have prognosticated within reasonable time (6 hrs) before the 96 hrs we recommend that you report this as a protocol deviation and that you enter all data into the prognostication form of the eCRF

- Should we perform neuroprognostication at 96 hrs in a patient that is still affected by sedation or should we wait until the next day, withholding further sedation?

  The protocol leaves you both options and you may choose which is more practical;

  1. *Prognosticate at 96 hrs. This patient will not fulfil the protocolized criteria for a "likely poor neurological outcome" since the A criteria states that* "Confounding factors such as severe metabolic derangement and lingering sedation has been ruled out". After further observation you may reconsider the prognosis. If the patient does not recover you may decide on a WLST due to a perceived neurological prognosis without violating the protocol. Report your reasons for WLST in the eCRF as "other" and specify the poor neurological prognosis and the reasons for it.

  2. *Wait another 24 hrs without sedation and prognosticate at this time-point.*

- If we reassess the neurological prognosis, should we fill in the prognostication form in the eCRF twice?

  No, you only fill in the form once. The data on further diagnostic examinations (EEG, CT etc) should anyhow be reported in the eCRF.

- During the weekend, a patient in coma was moved to a regular ward due to a shortage of ICU-beds. The patient is 96 hrs post-randomisation on the Monday and still unconscious. Should this patient be prognosticated?

  No, only patients still in the ICU at 96 hrs should be reported. However, you should investigate the reasons for moving the patient to a regular ward. If the patient was unconscious at the time of transfer this probably reflects a WLST decision and should be reported as such.

- A patient is fully awake in the ICU 96 hrs after randomisation and waiting to be transported to the general ward. Do we really need to perform a formal neuroprognostication?

  Yes, this is a necessary precaution against bias but it will be a very easy and rapid task!

- Is there any situation where the trial protocol mandates WLST?

  No

Personnel

- We have highly skilled nurses in our department who are very familiar with prognostication, can they perform the prognostication if they are blinded?

  No, prognostication should be performed by a physician experienced in neuroprognostication.

NSE

- We have used NSE for many years but haven't validated our cut-off for a poor prognosis. Can we still use this criteria in a patient in whom we are sure that the value is highly pathological.

  Yes. If you trust your method and your cut-off it can be used. In fact, it is quite difficult to perform a local validation due to the lack of standard.

Neurophysiology

- Our neurophysiologist reported that the patient had status epilepticus. Is this a malignant pattern?

  The TTM2 EEG classification avoids the term status epilepticus (SE) since there is no universal agreement on how to classify SE. Ask your neurophysiologist to use the TTM2 EEG-terminology to avoid misunderstandings. Be aware that there is substantial overlap between highly malignant EEG and SE.

- The EEG-report states that the reactivity to external stimuli (sound and pain) is unclear and difficult to assess. How should we report this finding?

  In the eCRF you are asked whether the EEG is reactive to external stimuli – yes/no. If the report doesn't state that there is a reactivity to either sound or pain stimuli you should answer the question by "no". Ensure that your neurophysiology dept perform reactivity testing according to the TTM2-trial EEG-instructions and consider repeating the examination.

- The SSEP-report states that the N20-responses are difficult to evaluate due to artefacts, how should we report?

  The eCRF question regards whether the N20-responses are bilaterally absent – Yes/No. To answer this question necessitates a registration with good quality (acceptable noise/artefact-levels and assessment of the conventional peripheral and subcortical components for quality control). If the presence of N20-potentials cannot be excluded due to poor quality or the registration is inconclusive for other reasons you should repeat the examination or answer this question by "no". Comment: Muscle relaxants is often useful to reduce artefacts.

Help

- What should we do if we have further questions on neuroprognostication in the TTM2?

  Please send an e-mail to ttm2@ttm2trial.org
  or contact Dr Cronberg directly at Tobias.Cronberg@skane.se