

Frequently Asked Questions (FAQS) Eurotherm3235 Trial August 2010

Q. Could you clarify the exclusion criteria? It says that a patients will be excluded if therapeutic hypothermia has been used or being used. Does this include therapeutic hypothermia to treat hypothermia to 35-36 degrees?

A. Patients can be included in the trial if temperature is greater than 36 degrees. Patients that have been cooled to below 36 degrees cannot be included.

Q. Is the randomization done by the internet?

A. Yes. All data is entered on the electronic case report form (e-crf) and randomization is completed via the e-rcf.

Q. Can a patient with multiple trauma be enrolled?

A. Yes, patients with multi trauma can be enrolled. However, this is the decision of the ICU Doctor depending on the patient's haemodynamic stability.

Q. The patients who receive a decompressive craniectomy immediately after their admittance to the hospital - can these be randomized too once their ICP exceeds 20 mm Hg, as decompressive craniectomy is mentioned as stage 3.

A. Yes. Any post neurosurgery TBI patient with ICP monitoring and meets Inclusion/exclusion criteria can be included and Neurosurgeons agree.

Q. "You state in Stage 1 of Therapeutic management of traumatic brain injury that ventriculostomy±drainage is an option. In our centre we use mainly intraparenchymal probes - is that ok?". "

A. Yes it is ok to use this type of monitoring.

Q. You showed a GOS formular, I assume it's required to visit the patients, as the exam is not so valid via phone - correct?

A. The plan is to send out the questionnaires centrally, initially by post and if no response will follow up by phone or personal contact.

Q. Will there be some money for the participating centres for patients recruited to cover costs for travel to the patients for the GOS assessment, and entering all the data?

A. There is funding for each site of 400 euros for each randomised patient and data entered. Sorry we have no funding for following up patients.

Q. Why is it not allowed to give hypertonic saline to the hyponatriemic patients -at least at a slow rate to raise their NaCl slowly? Even if the BBB is damaged in the traumatised brain, it will reduce swelling in the rest of the brain?

A. You can do your normal practice. The hypertonic saline quote was just a caution.

Q How long should patients remain in the control group in stage 1 and 2 before moving into stage 3? Is there a minimum time required, for example 48 hours as for Hypothermia?

A. There is no specific time that a patient in the control group needs to remain in stages 1+2 before progressing to stage 3 therapies. The decision to progress to stage 3 therapies will be based on the patient's haemodynamic stability i.e. some patients may progress quickly to Stage 3 therapy and some may not require stage 3 therapies at all. Patients should ONLY progress to Stage 3 therapies (either Decompressive Craniectomy or Barbiturate infusion) if their ICP remains >20mmHg despite receiving stage 1 and 2 treatments.

Q. The SAE monitoring should be done up to 7 days or until the removal of ICP?

A. SAEs should be collected from the time a patient is randomised until the ICP monitor is removed

Q. Cardiac arrest should be considered an SAE?

A. Cardiac Arrest is not a specific SAE for the trial. An SAE for these patients will be captured as either CPP < 50mmHg for greater than or equal to 15 minutes or Systolic BP < 90mmHg for greater than or equal to 30 minutes.

Q. Within which time is it necessary to complete the CRF?

A. The CRF forms up to randomisation must be completed before the patient can be randomised. The remaining Days 1-7 forms should be completed as soon as possible however it is possible to enter them retrospectively if this is easier for the Investigator. All days 1-7 forms, follow up form and MOHS form MUST be completed by 28 days after randomisation.

Q. How much data will we have to provide daily, and will this data be entered into a web based data bank, or on paper forms?

A. Data will be entered by the site onto the e-crf database. All users will have a password for the e-crf.