

Frequently Asked Questions (FAQs)
Eurotherm3235 Trial
October/November 2010

Q. The rewarming guideline states that if the ICP rises, cooling can be paused and the patient re-cooled. Can this be done at any stage in the rewarming phase?

A. Yes. Re-cooling can take place at any time during the rewarming phase. There is no temperature cut off for re-cooling so if the patient is rewarmed to 36 degrees and then ICP becomes a problem, you can re-cool them if necessary.

Q. When the patient's temperature reaches 36 degrees during rewarming, what is your experience of rebound hyperthermia?

A. Our experience of rebound hyperthermia is varied in that that some patients develop it and others don't. We usually have the cooling device available for 24 hours after rewarming. This means the patient can be re-cooled to hypothermia if ICP becomes problematic and also means that we can initiate cooling to normothermia if the patient has rebound hyperthermia.

Q. Could it bias the results of the trial if the control group do not have a specific cooling device in place to treat hyperthermia?

A. As long as the patients in the control group are treated for hyperthermia (by some means) if it develops, it will not bias the results of the trial by not using a specific device.

Q. If the patients ICP bolt is removed; do we still need to continue to collect data on Core Temp and MAP?

A. No, once the ICP bolt is removed there is no requirement to collect further data on the ICP Measurement form.

Q. Is it an idea to continue with hypothermia after Day 7 (if ICP still >20) ? or it is possible to rewarm the patient .

A. There is no maximum duration of hypothermia. In some cases, treatment may be required to achieve normo-thermia, i.e. stop rebound hyperthermia and high ICP after rewarming.

Q. Patient in the treatment group (HT + () standard care)- ICP will not decrease under 20 mmHg. How long to continue that treatment, when do we start stage 3 options? Do we continue hypothermia, if stage 3 treatment is started? Do we continue filling of eCRF until Day 7?

A. Once randomised to standard care and hypothermia, hypothermia should be titrated, with or without hypertonic therapy as you would usually do to try and achieve ICP<20mmHg. If escalation is required you should do what you usually do - barbiturates or decompressive surgery. If using barbiturates, I suggest loading with barbiturates then slowly rewarming as the combination (hypothermia & barbiturates) is associated with poor outcome. As this is a pragmatic trial, the answer is to do what you would have usually done, in both groups, but with hypothermia in the intervention arm.

Yes the CRF should be completed until day 7.

Q. I understand that if ICP is in place it is mandatory to fill eCRF until Day ? not more.

A. Please complete the daily forms until Day 7. If the ICP monitor is removed before Day 7 then the ICP measurement form does not need completed.

Q. Hypertonic Saline (avoid in hyponatraemic patients) - is there any number 130? 128?, is the reason for that risk of myelinolysis?

A. If this is your usual practise, please use it. It is only a guide. There is no evidence that hypertonics cause myelinolysis when the Na⁺⁺ is at these levels.

Q. Inotropes or vasopressors- is there difference?

A. Please use what ever you would usually use in your ICU. With the large number of patients that we will randomise, these small variations should be equal in both groups.

Q. Patient in the contr. group-> T increase (> 37,5 C?), can we controll feaver ? How? How deep?- 37C?

A. If you use fever control in your clinical practise, you do not have to change what you do. Patients' temperature in the control group should be maintained at normothermia.