An ICU Sedation Study

https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/ukcrc-studies/a2b

@A2BTrial

FAQs – August 2019

Q: Is Propofol is classified as an IMP for A2B and does the prescription need to be signed off by someone on the delegation log?
A: The propofol is considered an IMP for the trial (it's included in the Summary Product Characteristics etc.), but its use represents a continuation of standard care and as eligible patients will already be prescribed propofol, a new trial prescription, written by someone on the delegation log is not required. The existing propofol prescription, prescribed by whoever prescribed it originally, can continue to be used throughout the trial.

Q: We are screening a patient who is currently receiving propofol and clonidine. Would this patient be eligible?
A: If they are mainly sedated with propofol, they would still be eligible, so long as the clinical team is prepared to follow any of the 3 possible randomisation allocations as below:

- ***Propofol*** *- propofol continues to be the main sedative agent (clonidine could continue to be used as an adjunct e.g. to manage agitation, if necessary)*
- ***Clonidine*** *- attempt to down titrate the propofol and up titrate the clonidine*
- ***Dexmedetomidine*** *- team would have to be prepared to stop the clonidine*

Q: We don't do ALT as standard. We do AST. How should we record this?
A: Just leave the field blank if you don't measure ALT. A query will be generated by the blank field, so just go into the data query tab and add a comment to explain that ALT is not measured.

Q: Can we share anonymised ICE Q forms with the ICU clinical staff? I'm sure that the clinical nurses would be interested in the responses.
A: Unfortunately there is potentially a risk of people changing their practice based on feedback from the ICE questionnaires, so in order to be consistent throughout the trial it would be best not to share the data collected and for clinical staff to wait until the study is analysed and published – sorry!

Q: How should unplanned surgical debridement of necrotising fasciitis be entered in the reason for admission details?
A: The eCRF is being updated to include an "other" option, so that you will be able to enter this once the update has been approved, but for now, you can leave this blank.

Q: Are patients with neurological infections. (e.g. meningitis or encephalitis) eligible for A2B?
A: Yes, patients with neurological infections are eligible. Only acute brain injury is an exclusion.

Q: Do we always have to wait 2 hours from the confirming eligibility before randomising a patient?
A: No, the REC wanted us to give Personal Legal Representatives 2 hours to attend the ICU, before we use a Professional Representative or failing that, deferred consent. However, if they are present, you can randomise as soon as you have consent from a Personal Legal Representative.

Q: On the eCRF Screening Log, where should we record the reason for Consultant refusal?
A: You can record this in the "Reason why eligible patient was not randomised (other reason)" field.

Q: Our patient developed a cuff leak and had to be re-intubated (emergency procedure). Do we record this as an extubation in the eCRF or are you just wanting to capture the planned extubations?
A: We want to capture all extubations and intubations (as they could be related to sedation state).

Q: Who 's the best person to use as the Professional Legal Representative (ProfLR)?
A: The ProfLR must be independent of the Research Team (i.e. not be listed on the delegation log), and they should not provide health care under the direction or control of one of the Research team (e.g. a junior doctor). Ideally, the best person to approach would be the Consultant primarily responsible for the patients' medical treatment. Failing that, you should approach a person nominated by the "relevant health care provider" (e.g. the Trust). However, if your Trust hasn't nominated ProfLRs, then you can reasonably go to another ICU Consultant. If there isn't another ICU Consultant, you could ask a Consultant from a neighbouring department, or another professional, if this has been pre-arranged.

Q: If a patient is admitted at the weekend and is outside of the 48-hour window for inclusion by Monday when we recommence screening, do we add them to the screening log then?
A: Yes, we want you to log all the patients who are mechanically ventilated when you screen.

Q: When is the Clinician (A2B Clinician PISCF V2 03AUG2018) consent form to be used?
A: This form is only for use as part of the Process Evaluation. A copy needs to be kept in the ISF, but otherwise, you can ignore this form. For Professional Legal Representative Consent you should use either pre or post randomisation A2B Professional Legal Rep PISCF.

Q: Once the primary end-point is achieved, if a patient is subsequently re-intubated (>48hrs) do they need to be sedated on the arm that was selected for them in the trial?
A: No, once the primary endpoint is reached, the choice of sedative is up to the clinician looking after the patient. If a patient is re-intubated within 48 hours of extubation, then the trial sedation should be restarted/continued.

Q: Is it OK for the bedside nurse to stop the Dex/Clonidine prior to extubating, or do we need to continue them until after extubation?
A: The timing of discontinuation of IMP is at the discretion of the clinical team. This may include discontinuation prior to ending mechanical ventilation (e.g. patients with a trache), or discontinuation after extubation (e.g. for agitated or delirious patients)."

Q: Our patient wasn't intubated for more than 48hrs. What do we need to do about this?
A: Inclusion criteria 5&6 are about expected periods of ventilation. If these expectations are not met, you don't have to do anything about it other than recording the data in the eCRF.

Q: RE 30 days follow-ups – there are 2 types of EQ-5D-5L (one for phone) and ICE-Q. How should we do the 30 day follow-up and do you have a covering letter if posting questionnaires?
A: Try to follow-up by phone if possible. Use the phone version of the EQ-5D-5L for this along with ICE-Q. If you can't get hold of the patient by phone, post them the standard EQ-5D-5L and ICE-Q (there is a covering letter for this). Remember that 2 xEQ-5D need to be completed at 30 days, one for how the patient is feeling now and one about how they felt prior to their hospital admission.

Q: Does 'Rescue medication' just mean PRN medications? If a patient is on regular doses of NG Quetiapine, where should I record it?
A: The rescue medication section is meant to record all of the other medication given for agitation or delirium that hasn't been recorded in the Sedative details section. So, NG Quetiapine should be recorded in the rescue medication section (because it's not IV), provided your investigator considers it to be a rescue medication for agitation or delirium. If it's being given because the patient took it before ICU (e.g. for depression), then it needn't be recorded at all.

Q: If the 30, follow-ups are not collected because we have been unable to contact the patient by phone and postal questionaries' are not returned, would this be classed as a deviation?
A: Yes, this should be recorded as a deviation, because the questionnaires are secondary end points and compliance with secondary end points is checked throughout the trial.

Q: If patient randomised to dex or clonidine, but this is stopped and the patient is started on another sedative. Would this be classed as a deviation?
A: This is not a deviation (or violation) as the protocol allows flexibility and the switch over is being captured on the CRF. However, it would be a violation if the patient was on clonidine and had crossed over to dexmedetomidine or vice versa.

Q: If a patient is re-intubated during their ICU admission, does the re-intubation start a new 48-hour screening window?
*A: No, the 48-hour window is from the start of **first** ventilation in the current ICU admission.*

Q: After an Eligibility Checklist was signed by the ICU consultant, the patient's family refused consent, so the patient wasn't been entered into the trial. What should we do with the signed eligibility form?
A: Keep this (screening) information in the Trial records with a note to explain what happened.

Q: We screened a patient detained under section 37 of the Mental Health Act. Is it ok to recruit this patient?
A: Patients detained under section 37 of the Mental Health Act should not be included in the trial. Exclusion 15 "Prisoners" excludes Section 37 patients too.

Q: We have a patient whose 48hr post extubation period ends at 09:30. Do we fill in daily data for this hour and a half of the day, or for the 12hr dayshifts, or for the full 24hrs?
A: Please collect data for the full 24 hours, as some of the data collected on the daily data form is for that whole period.