An ICU Sedation Study

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

@A2BTrial

FAQs – November 2019

Q: Do we need to keep propofol running for patients in the dexmedetomidine and clonidine arms, so that it can be bloused to control agitation?
A: You need to have propofol boluses prescribed and readily available to manage agitation quickly for safety. Iit's especially important to consider how this will be achieved if the patient has been successfully weaned from a continuous infusion of propofol. If propofol is no longer required as a continuous infusion, you should either keep propofol hanging/attached or ensure that propofol is readily available to be drawn up in a syringe at the bedside.

Q: Should we be sending a letter to Trial patients' GPs?
A: No, the Ethics Committee didn't feel that a GP letter was necessary because by the time the patients saw their GP, the Trial intervention would be long finished.

Q: If we know that there aren't going to be any Personal Consultees, do we still need to wait 2 hours after confirming eligibility before we can randomise using Professional Consent or deferred consent?
A: Yes, even if you are confident that there won't be any Personal Consultees, to comply with the protocol and approvals, we are obliged to wait 2 hours before using another form of consent.

Q: Is there a form to use when we defer consent?
A: No, there isn't a form, but you should document the process in the patient's medical records, explaining why consent has been deferred and how consent will be sought subsequently (ASAP from either Professional and/or Personal Legal Representative Consent, depending on which is available first).

Q: If the patient's weight is between the (5kg) increments on the Infusion table what weight should we use?
A: If you're using the dosing tables, just round to the nearest 5kg. If your patient weighs less than 45 kg, contact the Trial Office for advice before randomising and if they weigh more than 100kg, dose as per 100kg column on the table.

Q: How should we use clonidine or dexmedetomidine if the patient requires deep sedation for clinical reasons?
A: The way deep sedation is maintained is under the guidance of the clinical team, but it is suggested that for patients receiving dexmedetomidine or clonidine these drugs are titrated up to the maximum tolerated dose according to the infusion algorithm. If additional sedative drug is needed to achieve target sedation this can be achieved with propofol or benzodiazepine according to the preference of the caring clinician.

Q: If we have a potential participant, but think they're unlikely to comply with follow-up, should we still recruit them?
A: Yes, it's difficult to guess which patients are going to complete follow-up, but not looking likely isn't an exclusion and we should still be able to collect primary outcome data for most patients, so include these patients anyway.

Q: Can we co-enrol patients into A2B if they are taking part in non-interventional studies that don't have co-enrolment agreements (e.g. studies that only involve questionnaires or blood samples)?
A: Yes, you can co-enrol patients in observational studies without any co-enrolment agreement – just record the name of the study under the Pre-randomisation tab of the eCRF.

Q: On Day 1 do you still want the ventilation obs. recorded nearest to 10am, even if the patient wasn't randomised until later and do you want the drugs recorded for the whole 24-hour period or just from randomisation until 07:59?
A On Day 1 just use the ventilation obs. nearest to 10am, even if the patient wasn't in the trial then. Only record the sedatives used from randomisation until the end of Day 1.

Q: What should we do if we don't have a blood result available?
A: Just leave the field blank; then explain in the resulting query that no result was available.

Q: Should we exclude a patient who has suffered a previous brain injury?
A: If the Acute Brain Injury was part of the patient's current acute illness (i.e. it either precipitated or complicated their current hospital admission) then they should be excluded, but if it was part of a previous hospital admission and now represents their baseline state, then they need not be excluded because of it.

Q: Should downsizing of a tracheostomy tube be recorded in the "Extubation Details" section of the eCRF?
A: No, the patient will only have been extubated (de-cannulated) momentarily to facilitate this change, which isn't really a re-intubation, by the same reasoning.

Q: Can dexmedetomidine or clonidine be given peripherally?
A: Yes, both dexmedetomidine and clonidine can be given peripherally, if necessary.

Q: Is it a problem if our pharmacy changes supplier of the dexmedetomidine or clonidine during the study, so that they provide us with different sized vials?
A: No, the IMPs for A2B are defined only by the active agents, so provided you infuse the correct final concentrations for the Trial (Dexmedetomidine 8micrograms per ml and Clonidine 15 micrograms per ml) it doesn't matter how the drug is packaged or which brand is used. Also, you can make the infusions up in whatever volume you choose to suit individual patients.

Q: Should other liver conditions exclude patients from A2B or is it only fulminant patients that are excluded?
A: The only relevant exclusion is "8-Fulminant hepatic failure", but if the treating Consultant has specific concerns relating to an individual patient's liver function, they could always decline to allow the patient to take part in the Trial. You should then record the patient on the screening log as eligible but not randomised because of "e-Consultant refusal" stating their given reason.

Q: Can a patient who has been previously intubated in ICU on this hospital but separate ICU admission be eligible?
A: Yes, their eligibility is based on the 1st 48 hours of ICU mechanical ventilation for the current ICU admission, so a patient could be eligible even if they've been in the ICU already, provided they weren't previously enrolled in A2B.

Q: What happens if a patient is transferred to another ICU before they are successfully extubated?
A: If the patient is transferred to another ICU, you need to select "transferred to other ICU" in the "Study ICU Discharge" Data, and also complete the "Other ICU Discharge Data" section, with details of their final ICU discharge there. You'll have contact the other ICU(s) to confirm whether the patient reached the primary outcome (ended mechanical ventilation followed by 48 hours of spontaneous breathing). If they did, then try to find out from the other ICU at least the date that this was achieved (and the time if possible) and record these in the "Final Extubation Details" section of the eCRF.