An ICU Sedation Study

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

@A2BTrial

FAQs – April 2019 (no 1)

Q: Does diverging from the algorithms constitute a protocol deviation?

A: No, the algorithm is a guide to operationalisation of the protocol advice, but does not itself appear in the protocol. We accept that bedside nurses will not always follow the algorithm faithfully, but we can see from the eCRF how much of each sedative has been used, the RASS scores recorded and whether there was a reason for any deep sedation.

Q: Are liver transplant patients

A: Yes liver transplant patients are eligible (fulminant patients are excluded)

Q: If a patient comes off ventilation but is re-intubated, are they eligible

A: We only want to recruit patients within 48 hours of their first period of mechanical ventilation in the ICU, so a reintubated patient would only be eligible if they were still within the (original) 48 hour window.

Q: What dose should I use for a 76kg patient?

A: When using the Dosing table, you should round up to the nearest weight. If the patient's actual weight is 76kg, you should follow the dosing table for an 80kg patient.

Q: What dose should I use for a patient that weighs more than 100kg?

A: You should use the Dosing Table column for ≥100kg patients

Q: If propofol has been stopped for a patient on clonidine or dex, would it be a good idea to keep the infusion connected?

A: Yes, the first line management for agitated patients is to bolus propofol, so make sure that propofol boluses are prescribed and advise the nurses to keep the propofol connected.

Q: If we reach the maximum dose of dex or clonidine can we use additional sedation?

A: Yes, if you follow the flowchart, you will see that it's intended to up titrate the dex and down titrate the propofol as much as possible, but propofol (and possibly other sedatives) may need to be used too for some especially difficult patients. But, remember, agitation may be resolved by considering other factors, e.g. pain or ventilator dyssynchrony etc. (as per flowchart).

Q: Our usual care is propofol + opiate. If we are having difficulty weaning the patient we might consider adding clonidine or Dex to facilitate reduction of sedation. Could we still do this for an A2B patient in the usual care arm of the Trial?

A: We recognise that dex and clonidine may need to be used sometimes, as part of usual care and we will capture this use on the eCRF, but we don't want patients in the usual care arm given so much of either clonidine or dex that propofol is no longer the main sedative agent.

FAQs – April 2019 (cont.)

Q: Can we give clonidine to patients in the dexmedetomidine arm?

A: No, you must never give clonidine to patients in the dex arm or vice versa as this crossover would constitute a violation.

Q: We don't usually use dex at 8 micrograms per ml. Do we have to use this concentration for the Trial?

A: Yes, we have to use the concentration detailed in the protocol. Also, both dex and clonidine have to be diluted in 5% glucose NOT saline (we're going to update the protocol so saline can be used too but at the moment it's just glucose that can be used).

Q: Do the study drugs need to be specially labelled (Annex 13) labelling?

A: No special labelling is required

Q: Should patients be excluded if they're needing deep sedation at the time of screening?

A: No, there is no requirement that the patient must be for light sedation at the time of recruitment and we want to recruit patients who initially need deep sedation too. If these patients go into the trial, then we will capture the reason for deep sedation on the Shift Forms (and so the eCRF).

Q: Can we recruit patients who might need to be paralysed later in their ICU stay?

A: Yes, so long as the patient is not requiring paralysis at the time of recruitment then you can recruit them to the trial. Remember too that if paralysed patients are screened early in the 48 hour period, it may be possible to re-screen them later, in case paralysis is discontinued before the end of the 48 hour window.

Q: Are patient Study numbers allocated by the Trail database?

A: Yes, when you create a new patient on the database prior to randomisation, this will generate a patient number

Q: Does the 48 hrs screening window include time outside ICU e.g. in ED or theatre?

A; No, we're looking for patients within 48 hours of the starting mechanical ventilation for the first time in the ICU, so if they were transferred from another ICU where they were ventilated that time would count but if they have come straight from theatre/ED, you should use the time of ICU admission as the start of ventilation.

Q: In the Pre-Randomisation Data form (Data V1.0 25-Apr-2018) who should the Investigator signature be? PI? Doctor? Or anyone on the log?

A: It has to be a medic who confirms eligibility and they have to be on the delegation log too and delegated that task

Q: On the Daily data collection form PG 6: Event Details: unplanned line removal is this with regards to the patient only or staff as well e.g. if the staff accidentally removes an atrial line?

A: We want you to record if lines etc. have been removed as a result of poor sedation e.g. if the line was removed as a result of the patient being agitated

FAQs – April 2019 (cont.)

Q: Who can prescribe the trial IMP?

A: The person prescribing the clonidine or dex after randomisation to A2B should be delegated to do so by the PI on the delegation log and should have completed GCP and LearnPro or SIV training. However we can provide an abbreviated GCP training for anyone who will only be confirming eligibility or prescribing IMP.

Q: Are only doctors allowed to prescribe Trial Clonidine or Dex?

A: No, the IMP does not necessarily have to be prescribed by a medic, it can be prescribed by a consultant nurse/supplementary prescriber as long as they are delegated to do so and local Board policy allows for this (i.e. does not have any specific requirement for IMPs to be prescribed by a doctor).