ABBRUPT FAQs

Q. Can ACCPs confirm eligibility?

A. Yes, following the protocol amendment to v3.0 dated 30th July 2024.

Q. K levels of <4 mmol and Mg levels above your hospital's index lower level of normal **prior to randomisation?**

A. Yes, in order to confirm eligibility, normal electrolyte management should have taken place. Once magnesium and potassium have been replaced these do not need to be retested in order to meet this inclusion criteria.

Q. Will ICU level 0 and 1 be included?

A. Yes, any patient in an ICU who meets the eligibility criteria can be included in the trial.

Q. Can I start on metoprolol but if not working switch to amiodarone?

A. Crossover is not permitted within the protocol, but it is what is best for patient care. If an alternative treatment is started to treat AF, this will be captured on the follow up forms. A Change of Status form will also need to be completed withdrawing the patient from the trial treatment although the patient remains in the trial and is followed up in the usual way.

Q. If randomised to amiodarone, how long do I have to wait before trying something else, eg beta blockers?

A. We would recommend you aim for an effect (either cardioversion to sinus rhythm or a slowing of ventricular response) within 4 hours and re-dose accordingly.

Q. Can you explain the consent process?

A. ABBRUPT is using deferred consent as patients are likely to lack capacity to consent for themselves. For potential participants who are deemed eligible, the first approach will be made by their clinical care team. The decision to take part in the trial will be entirely voluntary. If a patient/legal representative does decide to take part, the research staff delegated the duty to take consent, will ask the patient/legal representative to read and sign the consent form having been provided with the Patient/Legal Representative Information Sheet. Consent from a patient/legal representative will be sought as soon as practically possible. Sites should aim to obtain consent within 72 hours of the patient being randomised into the trial.

Q. Can an alternative treatment to the randomised treatment be given to treat NOAF (i.e. the patient has not maintained sinus rhythm for 24 hours)?

A. Yes, it is what's best for the patient's care. However, if an alternative treatment to the randomised treatment is given to treat NOAF, please complete a Change of Status form to confirm the randomised treatment has been stopped. The patient will remain in the trial and will be followed up in the usual way.

Q. If a patient's magnesium level is below the hospitals' lower level of normal, can magnesium be given to increase the magnesium level to meet the eligibility criteria?

A. Yes. We would expect sites to correct and supplement electrolytes before randomisation.

Q. If a patient develops NOAF whilst in theatre but will be going to ICU from theatre; can they be included in the trial?

A. No. Intranet and perioperative AF may have different triggers and the treating team may change after transfer from theatre to ICU.

Q. If a patient has fast AF and receives cardioversion and goes back into sinus rhythm but then develops AF, can they be included?

A. Yes, these patients can be included if it is deemed to be the same initial episode of NOAF as determined by the treating clinician..

Q. If a patient has a previous history of SVT, can they be included?

A. Yes, unless it is documented that the SVT is AF. SVT comprises many arrhythmias, AF being one of them. But often patients have SVTs other than AF, and we may not be able to specify further from the history.

Q. Can you 'switch' from beta blockers after you've obtained sinus rhythm with amiodarone?

A. Yes, once sinus rhythm has been achieved for 24 hours using the randomised allocation, if the patient goes back into AF, the patient can be treated as per standard of care. The additional drugs will be recorded on the follow up forms.

Q. Can you re-load amiodarone and can you give amiodarone without the loading dose?

A. Yes, you can re-load amiodarone. The dose, route and duration is entirely down to the clinical team.

Q. If you give beta blockers and AF rate remains uncontrolled, can you give amiodarone or is this a protocol deviation?

A. Yes you can if that is what is best for the patient. We ask that you note on the CRFs when the randomised treatment was stopped, and a Change of Status form is completed to advise that the 'researcher' has decided to stop the randomised treatment. This way it is not a protocol deviation.

Q. If you give DC CV is that a protocol deviation?

A. DC CV is a safety outcome and is recorded on the follow up CRFs. This will not be a protocol deviation.

Q. Would a chest drain exclude a patient?

A. Yes if the chest drain was inserted as part of a surgical procedure performed in theatre. If the chest drain is inserted in ICU, and the patient meets all other criteria, the patient can be included in the trial.

Q. If a patient presents with NOAF, is treated with usual electrolytes and goes back into sinus rhythm but then goes into AF again can they be included?

A. If the clinician intents to treat it, then yes, the patient would be eligible for the trial.

Q. If a patient has NOAF for 18+ hours would they be eligible?

A. As long as it is still NOAF (i.e. the treating clinician deems it to be the same episode of AF) then yes they are eligible for the trial.