ABBRUPT FAQs

Q. Can ACCPs confirm eligibility?

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

Q. Potassium level of <4 mmol **prior to randomisation?**

A. Yes, in order to confirm eligibility, normal electrolyte management should have already taken place according to your site practice. Once potassium has been replaced, this does 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. Ideally, we would like the randomised treatment to be given until sinus rhythm has been maintained for 24 hours.

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. If it is not deemed appropriate to approach the personal legal representative, a professional legal representative should be sought.

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 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 the treating clinician is going to treat with either amiodarone or beta blockers.

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. No, chest drains are permitted as are oesophagectomies.

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

A. Yes, the patient would be eligible for the trial.

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

A. If the treating clinican is going to treat the patient with amiodarone or beta blockers, yes, they would be eligible.

Q. Can a patient with atrial flutter be included?

A. No. ABBRUPT is looking at atrial fibrillation only.

Q. If amiodarone has already been given, can the patient be randomised?

A. Yes if the treating clinician has equipoise and is willing to switch to beta blockers (if that is the randomised treatment).

Q. If amiodarone loading dose is currently being given, can the patient be randomised?

A. We would ask that the infusion is completed first as the patient may go back into sinus rhythm. If AF persists and the treating clinician has equipoise and is willing to switch to beta blockers (if that is the randomised treatment), then yes, the patient can be randomised into the trial.

Q. If potassium level is <4 mmol, has been replaced but remains <4 mmol, can the patient be recruited?

A. If there is a clinical intention to replace the potassium, yes, the patient can be included.