| For your contact details to be passed on to academic third parties | No | Yes |
| --- | --- | --- |
| For your contact details to be passed on to commercial third parties | No | Yes |
| Under the current UK Data Protection Regulations, the University of Birmingham must make any records pertaining to you available upon written request.  To do so please contact Legal Services (legalservices@contacts.bham.ac.uk), University of Birmingham, Edgbaston, Birmingham, B15 2TT.  A small charge may be made. Your details will be kept indefinitely.  Your records are regularly reviewed and updated.  If you find any of your details are incorrect, please contact the **ABBRUPT** Trial Manager at the BCTU. |

| **For new centres wishing to participate in the ABBRUPT trial**The lead local researcher for a multi-centre Trial is the local Principal Investigator. This role carries certain responsibilities:* Day-to-day responsibility for the conduct of the research
* Responsibility for ensuring the agreed protocol is followed
* Helping care professionals ensure participants receive appropriate care while involved in the research
* The integrity of records and ensuring they are kept confidential
* Reporting adverse reactions

All research sites require approval from the Trust/Health Board Management that the research may take place. No patients can be approached for consent until all approvals are in place.The **ABBRUPT** Trial Office can assist in the approval process if the following information is provided. The Trial Office will complete the necessary paperwork and return to the PI for signature and submission. * It is the role of the Trust/Health Board to assess whether the local PI has the necessary training and experience to undertake the research described in the proposal.
* The Trust/Health Board will want to have some indication of relevant recent research experience and current research commitment. This is usually a recent certificate of attendance at Good Clinical Practice (GCP) course.
* The Trust/Health Board needs to know other members of the research team who will have a significant research role (e.g. Staff who will consent patients, research nurses, clinicians). Do not give names of individuals whose involvement is part of their normal service duties.
* All researchers should comply with the requirements of the UK Policy Framework for Health and Social Care Research. This document can be found at: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>
* The Trust/Health Board will also wish to be reassured that the PI has time to undertake the proposed project and sufficient time to supervise any other staff involved in the project.
* The Trust/Health Board will want reassurance that the person taking consent locally is appropriate for the task, by being aware of the nature of that process and familiar with “best practice” and that this person should have sufficient time and expertise to answer all questions that might be raised by the trial participants.
* The Trust/Health Board will want to see the participant information sheet and trial consent form on Trust/Health Board headed paper. If you can send us a blank sheet, we will print off a batch of forms for you.
* Your local PALS office (or equivalent) will serve as a source of independent advice for participants.
* The Trust/Health Board will also want to know whether there will be any local deviations from the protocol, how are participants identified for the trial and who makes the first approach. This form will help the **ABBRUPT** Trial Office work the protocol around your local practice.
 |
| --- |
| **IMPORTANT: Current UK Data Protection Regulations**In providing this information, you agree for your contact details to be retained on a database maintained by the Birmingham Clinical Trials Unit (BCTU). From time to time, we may contact you in order to update you about our clinical trials, or to invite you to relevant trials meetings. We would be grateful if you would take the time to complete the following consent statements relating to the storage and handling of your contact details:**Please indicate whether you give consent:** |

**Trial Summary**

| Title | The ABBRUPT Trial: A randomised controlled trial to investigate clinical and cost effectiveness of Amiodarone vs Beta Blockade for new onset atrial fibRillation in icU - a Pragmatic sTudy |
| --- | --- |
| Acronym  | ABBRUPT |
| Objectives | To conduct a multi-centre, randomised trial comparing two commonly used treatments (beta blocker and amiodarone) for New Onset Atrial Fibrillation (NOAF) in intensive care.The economic evaluation will compare beta blocker with amiodarone from a National Health Service (NHS) and Personal Social Services (PSS) perspective. A within-trial cost-effectiveness (CEA) and cost-utility analysis (CUA) will be conducted at 90-days follow up. If the trial demonstrates a difference between strategies, a model-based CUA will extrapolate beyond the endpoint of the trial. |
| Trial Design | A pragmatic open-label interventional multi-centre two-arm randomised controlled trial with internal pilot and economic evaluation. |
| Target Population  | Patients (≥16 years) in intensive care units (ICU) with NOAF (persistent or paroxysmal) for which therapeutic intervention is planned by the clinical team. |
| Eligibility Criteria  | Inclusion criteria* Patients in an adult ICU (age ≥16 years)
* Onset of NOAF during the acute illness (A&E, deterioration on ward, after surgery) having previously been in sinus rhythm and not known to previously have had AF.
* A minimum duration of AF of at least 30 minutes
* Usual electrolyte management with potassium and magnesium according to site practice
* A clinical indication to treat NOAF as determined by the attending clinician

Exclusion criteria* Any known previous documented history of AF, whether permanent, persistent or paroxysmal
* Receipt of amiodarone or a beta-blocker in the previous 24 hours
* Current concomitant medication with treatments that are contraindicated with the intervention / comparator medications
* Serum Potassium of < 4 mmol L-1
* Serum Magnesium of <1.0 mmol L-1
* Patients having undergone cardiac surgery during the current hospital admission, defined as any surgery including stent procedures such as percutaneous coronary interventions or other angioplasty procedures done on the heart muscle, valves or thoracic arteries including the thoracic part of the aorta
* Thyrotoxicosis
* Withdrawal of life support therapy within 24 hours
* Other thoracic surgery that ingresses the thorax
* Any other known contraindication or known sensitivity to beta-blockers or amiodarone
* Known pregnancy or patients currently known to be breast-feeding
 |
| Sample Size | 2560 patients |
| Setting | At least 60 Intensive Care Units across the UK with a track record of participating in critical care research. |
| Interventions armControl Arm | AmiodaroneAmiodarone will be given as a loading dose (usually 300mg over 1 hour) followed by a continuous infusion of (usually) between 300-1200mg (usually 900mg) per day with the treating clinician choosing the route of administration and duration.Beta BlockadeClinicans will be given a choice of beta-blocker: bisoprolol, metoprolol, esmolol, propranol, atenolol, labetalol, carvedilol, and landiolol. The beta-blocker choice should reflect local availability and familiarity. They may be administered enterally or intravenously; dosing should be according to local practice. |
| Outcome Measures | Primary Outcome• To assess 90-day mortalitySecondary OutcomesClinical Outcomes:• ICU and hospital mortality• Rates of cardiovascular events including stroke, myocardial infarction or thromboembolism up to 90-days• Rate of established AF by the end of ICU stay / death / Day 90Safety outcomes:• Number of episodes of bradycardia (HR <50 bpm)• Bradycardia and bradycardic arrhythmias with haemodynamic compromise requiring intervention• Significant hypotension requiring intervention• Heart block• Arrhythmia with haemodynamic compromise requiring intervention including DC cardioversionEconomic Outcomes: • Cost-effectiveness of the intervention• Health care resource use including ICU and hospital length of stay |

**Schedule of Assessments**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Procedure** | **Baseline** **(Day 0)** | **Day 1** | **Day 2** | **Day 3** | **Day7** | **ICU Discharge** **(± 1 Day)** | **Hospital Discharge****(± 1 Day)** | **Day 60** **(in hospital if necessary)****(± 14 days)**  | **Day 90****(± 14 Days)** |
| Eligibility assessment | ● |  |  |  |  |  |  |  |  |
| Consent |  |  |  | ● |  |  |  |  |  |
| Randomisation | ● |  |  |  |  |  |  |  |  |
| Prescription of IMP by clinical team | ● |  |  |  |  |  |  |  |  |
| Demographics (medical records) | ● |  |  |  |  |  |  |  |  |
| Medical history (medical records) | ● |  |  |  |  |  |  |  |  |
| Biochemistry | ● | ● | ● | ● |  |  |  |  |  |
| Cardiovascular | ● | ● | ● | ● |  |  |  |  |  |
| Blood sampling  | ●1 | ●1 |  | ●1 |  |  | ●1 |  |  |
| AF resolution  | ● | ● | ● | ● | ● | ● | ● |  |  |
| Expected Serious Adverse Events and Serious Adverse Events |  | ● | ● | ● | ● | ● | ● | ● | ● |
| Mortality and morbidity |  |  |  |  |  | ● | ● | ● | ● |
| Medications |  |  |  |  |  | ● | ● | ● | ● |
| Quality of life questionnaires (EQ-5D-5L) |  |  |  |  |  |  | ● | ● | ● |

| **Site Details** |
| --- |
| Trust Name |  |
| Hospital Name |  |
| Full address of hospital |  |
|  |
| Based on the trial summary, would your site be interested in taking part in the ABBRUPT trial? |
| Yes [ ]   | *Please complete the rest of short questionnaire below and return it to the trial office* |
| No [ ]  | *Please provide a reason:*  |
|  |
| **R&D Contacts Details** |
| Title and Name |  | Post held: |  |
| Telephone: |  | Email: |  |
|  |
|  |
| **Principal Investigator**The Principal Investigator (PI) is the clinician who will take full responsibility for the conduct of the trial at the site. This is usually a clinician who has hosted research in the past and this person will need to show evidence of up-to-date Good Clinical Practice (GCP) training. |
| Title and Name: |  |
| Post held: |  |
| NHS Trust / Health Board Employer: |  |
| Address: |  |
| Telephone: |  |
| Email |  |
| Does the proposed PI hold a current substantive or honorary contract with the NHS organisation named above?  | Yes [ ]  | No [ ]  |
| Is the proposed PI interested in participating in the ABBRUPT trial? | Yes [ ]  | No [ ]  |
| Is the proposed PI willing to adhere to the randomised allocation? | Yes [ ]  | No [ ]  |
| Does the proposed PI have previous experience in conducting trials?  | Yes [ ]  | No [ ]  |
| Does the proposed PI have current GCP training? | Yes [ ]  | No [ ]  |

| **Assessment of Recruitment capabilities** |
| --- |
| Please provide an estimate of how many adult patients are admitted to your ICU per month with NOAF: |
| *Enter response here:* |
| Of those patients, how many meet the eligibility criteria for the ABBRUPT trial?  |
|  |
| How many participants would you expect to recruit into the ABBRUPT trial per month?  |
| 0-3 [ ]  | 3-6 [ ]  | 6-9 [ ]  | 9-12 [ ]  | 12+ [ ]  |
| Is your site currently taking part in any other trials within the same patient population as ABBRUPT? |
| *Enter response here:* |
| Are there any factors that could impact your sites ability to recruit into the ABBRUPT trial? |
| *Enter response here:* |

| **Trial Logistics** |
| --- |
| Is your site able to conduct each of the assessments required for the ABBRUPT trial?  | Yes [ ]  | No [ ]  |
| Does your site have capacity to follow-up ABBRUPT participants at 60 and 90 days post randomisation? | Yes [ ]  | No [ ]  |
| Does your site routinely test women of childbearing age for pregnancy on admission to ICU? | Yes [ ]  | No [ ]  |
| Are there any factors that could impact your sites ability to complete assessments and follow-up participants taking part in the ABBRUPT trial? |
| *Enter response here:* |

| **Recruitment of non-English speakers***Note: Use of relatives to translate is discouraged.*  |
| --- |
| Please outline what services are available at your site? |
| Staff member with shared language [ ]  | Language line [ ]  | PALS [ ]  |
| Professional translator [ ]  | Other [ ]  (Please state): |

| **ABBRUPT Trial office main site contact***Please give a contact name for the administration of the trial at your site. This may be a Trial Co-ordinator, Research Nurse or a member of the administrative staff who will form the first point of contact with the ABBRUPT trial office.*  |
| --- |
| Name |  |
| Role: |  |
| Email: |  | Telephone: |  |

| **Are there any issues you foresee in the ABBRUPT trial? Do you have any questions?**  |
| --- |
| *Enter response here:* |

| **Checklist for document returns:** |
| --- |
| Completed Form | Yes [ ]  | No [ ]  |
| Principal investigator CV | Yes [ ]  | No [ ]  | To follow [ ]  |
| Principal investigator CGP certificate | Yes [ ]  | No [ ]  | To follow [ ]  |
| CV of other investigators  | Yes [ ]  | No [ ]  | To follow [ ]  |
| **Please return all the forms to the ABBRUPT Trial Office:****Email:** ABBRUPT@trials.bham.ac.uk **Postal Returns**ABBRUPT Trial Office Birmingham Clinical Trials UnitInstitute of Applied Health ResearchCollege of Medical and Dental Sciences Public Health Building University of BirminghamEdgbastonBirminghamB15 2TT  |