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**The clinical and cost effectiveness of Amiodarone vs Beta Blockade for new onset atrial fibRillation in icU - a Pragmatic sTudy (ABBRUPT)**

 LEGAL REPRESENTATIVE INFORMATION SHEET

**We would like to invite you to give permission for your relative/ friend/ patient to continue participating in the ABBRUPT trial.**

This Information Sheet tells you the purpose of the ABBRUPT trial, what has happened so far and what will happen if your relative/friend/patient continues to take part.

**Please note**: Continuing to taking part in this trial is entirely voluntary and will not affect your relative’s/friend’s/patient’s current or future NHS standard of care

| Trial Summary* Patients admitted to Intensive Care Units (ICU) with a serious illness can go on to develop new onset atrial fibrillation (NOAF) which requires urgent treatment.
* Atrial fibrillation (AF) makes the heart less efficient at pumping blood around the body and can result in a very fast heart rate. This can increase the risk of complications such as heart attack and stroke.
* Your relative/ friend/ patient was diagnosed with NOAF, assessed for eligibility and included in a national clinical trial called ABBRUPT.
* As part of the trial, they were treated with one of the routinely used treatments for AF. We do not know which treatment is better and ABBRUPT aims to discover which one (if any) is better
* Whilst they are in hospital, we can collect the majority of information that we need from their medical notes.
* After they are discharged from the hospital, we will follow-up them up by telephone to see how they are.
* Trial participation and information provided will be kept confidential and handled in accordance with the Data Protection Act 2018.
* A member of the research team will visit you soon. If you have any immediate questions, the team’s contact details can be found on the last page of this information sheet.
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**Invitation**

This information sheet is being provided to you because your relative/friend/patient has been included in a national clinical trial called ABBRUPT but they are currently unable to consent for themselves. In these situations, the law allows a legal representative to provide consent on their behalf.

A member of the research team will go through this information sheet with you to help you to decide whether or not you would like to give permission for your relative/friend/patient to continue to take part in this trial. Please do take the opportunity to ask any questions and request more information if anything is unclear. Feel free to talk to others about the study if you wish.

Continuing in this trial is entirely voluntary, and your decision will not affect your relative’s/friend’s/patient’s current or future NHS care. If you decide that they should continue in the trial, you can request that they stop being part of the trial at any time. We will keep and use the data collected up to the point of them stopping.

What is the ABBRUPT trial, and why is it being done?

Each year approximately 10% of patients who are being treated in an ICU will develop NOAF. We do not fully understand what causes NOAF in these patients but believe that it may be the result of a number of factors including:

* Normal body reactions to infection and injury
* Altered levels of electrolytes (salts) in a patient’s blood
* The drugs used to support a patient’s blood pressure
* Certain commonly used ICU procedures

Some of the studies to look at the risks associated with NOAF suggest that patients who develop NOAF whilst on the ICU seem to be at higher risk of complications such as heart attack and stroke, which means that they need to spend a longer time in hospital. Some patients who develop NOAF may also end up in permanent AF and require lifelong treatment.

We need to do a trial because we do not have a clear understanding of the best way to treat patients who develop NOAF whilst in ICU and currently, in the UK, a number of medications are used.

**What has happened so far?**

Your relative/friend/patient was admitted to the intensive care (ICU) because they were very unwell. Whilst there, they were found to have developed something called atrial fibrillation (AF). AF is a problem with the heart's electrical system that causes an irregular heartbeat. It makes the heart less efficient at pumping blood around the body and can result in a very fast heart rate. Sometimes, when patients are very unwell, they will develop AF for the first time. This is called 'new-onset AF’ (NOAF).

Your relative/friend/patient developed AF lasting for more than 30 minutes even though they do not have a previous history of the condition. They were therefore included in the ABBRUPT trial which is investigating whether treating patients who develop NOAF with amiodarone (a drug used to prevent heart rhythm disorders) is better than treating them with beta-blockers (a group of drugs that make the heart beat slower and reduce blood pressure). Both medications are routinely used to treat NOAF and will have been given to them according to usual care guidelines.

Ordinarily, we would ask for permission to include a patient in a trial before any research procedures take place, but because your relative/friend/patient was so unwell, we were unable to do this. Following consultation with clinicians, patients and carers with ‘lived experience’, it was determined that it would be in patients best interest to begin treatment first and then take consent later. We have special approval from a Research Ethics Committee to conduct emergency care research in this way.

The type of information we collect is described later in this Information Sheet.

All patients in this trial received usual care as per local NHS standard clinical practice.

A researcher from the ABBRUPT Trial Team will have collected most of the information needed from your relative’s/friend’s/patient’s medical notes, which had been recorded as part of routine care by their clinical care team. This information was entered into an online database, and the computer randomly allocated your friend/relative/patient to receive either standard treatment plus amiodarone or beta-blockers.

What would continuing to take part involve?

If you agree for your relative/friend/patient to continue taking part in the ABBRUPT trial, the researcher will ask you to provide your written consent.

Information will continue to be collected from relative’s/friend’s/patient’s medical notes including the results of tests that are done as part of their usual care.

A researcher will monitor their progress for 90 days from when they first joined the trial and will collect information on:

* Their illness and treatment during their stay in ICU
* The date they are discharged from ICU
* The date they are discharged from hospital
* How they are around 60 days later (30 minute telephone call if discharged)
* How they are at around 90 days later (30 minute telephone call if discharged)

Additionally, during their hospital stay, when they are discharged from hospital, at 60 days and at 90 days we will ask them to tell us about their health status using an EQ5D-5L health questionnaire.

During your relative’s/friend’s/patient’s stay in hospital, with your permission, a researcher will take some blood samples (20ml of whole blood, approximately four teaspoons) at four time points which will be used to undertake future ethically approved research in AF. The blood samples will be labelled with your relative’s/friend’s/patient’s trial number and will be stored at the hospital where are they are being treated.

With your consent, your relative’s/friend’s/patient’s GP will be informed of their participation in the trial, but they do not have access to the trial data that we will collect.

What are the possible benefits of taking part?

While there is no direct benefit or financial incentives for patients that take part in this trial, the information provided by the trial may help in the long-term, to improve and shape future care for ICU patients who develop NOAF.

What are the possible disadvantages and risks of taking part?

Both amiodarone and beta-blockers are widely used across the NHS and have been shown to be relatively safe. However, as with most medications, there are some common side effects associated with them, which include:

**Amiodarone**

* Bradycardia (slow heart rate)
* Hypotension (low blood pressure)
* Tremors
* Eczema
* Pain/ infection at the site of injection or drip
* Eye Disorders

**Beta-blockers**

* Bradycardia
* Hypotension
* Dyspnoea (shortness of breath)
* Dizziness
* Headache
* Fatigue (feeling tired)
* Nausea (feeling sick)

The medical team that are caring for your relative/friend/patient have closely monitored their health and will continue to do so. If you have any concerns about your relative/friend/patient taking part in the trial, please do not hesitate to talk to the medical team or a member of the ABBRUPT Trial Team.

There will be an independent safety committee that will review the trial data anonymously at regular intervals and on-demand where necessary to ensure that the trial is safe to continue.

How have patients and the public been involved in this study?

A group consisting of patients and members of the public helped to develop this research topic and the research questions that should be asked. A member of this group is also a co-applicant of the funding grant and will continue to be involved in the trial.

Patients’ opinions on the timing of consent, the study inclusion and exclusion criteria, frequency of patient visits and the assessments that will be carried out were considered when designing this trial.

Patients were involved in designing and reviewing this information sheet.

The conduct of the study is entirely in the hands of very experienced researchers and no patient and public involvement (PPI) group or lay person has access to your relative’s/friend’s/patient’s personal healthcare records or is able to influence their treatment.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect patients interests. This study has been reviewed and given a favourable opinion by the Research Ethics Committee (reference: 23/SC/0334).

Who is organising, insuring and funding the research?

The UK government funds this study through the National Institute for Health and Care Research, Health Technology Assessment programme (reference: NIHR150027).

The sponsor of this study is the University of Birmingham (reference: RG\_22-153)

The Birmingham Clinical Trials Unit (BCTU) coordinates the study at the University of Birmingham. A copy of your consent form will be sent to BCTU to ensure the trial is conducted correctly. Physical paperwork containing identifiable data will be kept inside a locked filing cabinet in an access-controlled and secured room. Electronic data will be held on secure, encrypted IT servers within the University of Birmingham.

No member of the Research Team is being paid for including you in this trial.

The University has in place Clinical Trials indemnity coverage for this trial, which provides cover for harm which comes about through the University’s, or its staff’s, negligence in relation to the design or management of the trial and may alternatively, and at the discretion of the University provide cover for non-negligent harm to participants. The NHS Trust has a duty of care to its patients, in the event of clinical negligence being proven, compensation will be available via the NHS indemnity.

Will my relative/friend/patient taking part in this study be kept confidential?

All information collected about your friend/relative/patient for this trial will be subject to the General Data Protection Regulation (GDPR) and Data Protection Act 2018 for health and care research and will be kept strictly confidential.

**How we will use information:**

The University of Birmingham (UoB) is the Sponsor for the trial and acts as the data controller for all information collected in the study. This means UoB has specific legal and ethical responsibilities for looking after participants’ information and using it properly. Further information on data handling can be found on the privacy notice at www.birmingham.ac.uk/ABBRUPT.

For this study, we will collect your friend/relative/patient’s name, gender, age, brief demographic data and medical history.

The only people allowed to look at the information will be the researchers at the hospital and BCTU who are running the study, the regulatory authorities and sponsors who check that the study is being carried out correctly. In all routine correspondence between the hospital and BCTU, your friend/relative/patient will be identified using their unique trial number and initials.

All information collected by the Research Team will be safely and securely stored in the ABBRUPT Trial Office at the University of Birmingham and will only be accessible by authorised personnel. People who do not need to know who your friend/relative/patient is will not be able to see their name or contact details. The only people at the University of Birmingham who will have access to information that identifies them, will be people who manage the trial or audit the data collection process.

By taking part in the trial and signing the consent form you will be agreeing to allow staff from the ABBRUPT Trial Office to look at your friend/relative/patient’s medical records. It may also be necessary to allow authorised personnel from government regulatory agencies (e.g. the Sponsor and/or NHS bodies) to have access to their medical and research records. This is to ensure that the trial is being conducted to the highest possible standards.

**What will happen to the study data?**

All trial data will be retained for at least 25 years after the publication of the research outcomes. Your relative’s/friend’s/patient’s trial data may be shared with other researchers to support related research in the future. Your relative’s/friend’s/patient’s name and contact details will be removed before doing so.

**What are your choices about how your information is used?**

You can stop your friend/relative/patient being part of the study at any time, without giving a reason, but we will keep information about them that we already have.

If you choose to stop your friend/relative/patient taking part in the study, we would like to continue collecting information about their health from their hospital and/or their GP. If you do not want this to happen, tell us and we will stop.

We need to manage their records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about them.

What happens if new information becomes available?

Sometimes we get new information about the treatments being studied. If this happens, the researcher will tell you and discuss whether your relative/friend/patient should continue to participate in the trial.

If the researcher is happy for your relative/friend/patient to continue in the trial, you will still have the option to decide whether they do continue. We may ask you to re-sign a consent form if you decide that they should. If the researcher considers that your relative/friend/patient should stop (the reason will be explained to you) or if you decide that you do not want your relative/friend/patient to carry on in the trial, the researcher will make arrangements for their usual care to continue.

What if there is a problem?

We do not anticipant that anything will go wrong. If you have any concern about any aspect of this trial, please speak to the clinical care team or the ABBRUPT Trial Team.

Regardless of this, if you would like independent advice or complain about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaint mechanisms will be available to you. In England and Wales please contact Patient Advice and Liaison Service (PALS) at your local hospital. In Scotland, please contact the Patient Advice and Support Service (PASS) and in Northern Ireland, please contact the Northern Ireland Public Services Ombudsman (NIPSO).. Contact details can be found on the end of this Information Sheet.

What will happen to the results of the research study?

The result of this trial will be published in peer reviewed journals and presented at medical conferences. A final report will be submitted to the NIHR Journals Library that is publicly accessible. A summary of the result will also be shared on the trial website. No personally identifiable information will be included in publications from this trial.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information:

* at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
* by asking one of the research team
* by sending an email to dataprotection@contacts.bham.ac.uk

There is also an open-access ABBRUPT trial website [www.birmingham.ac.uk/ABBRUPT](http://www.birmingham.ac.uk/ABBRUPT) which contains information about the trial. No identifiable information will be available on this website.

Do you have any further questions?

If you would like to speak to the research team about the study please contact:

| **Local Coordinator:** | **Principal Investigator:** |
| --- | --- |
| <Insert name, job title><Insert tel and/or email> | <Insert PI name, job title><Insert tel and/or email> |

For independent advice or support, you can contact your local NHS PALS:

Tel: *<insert local PALS contact number(s)>* Email: *<insert local PALS email address>*

Website: *<insert PALS website>*

For independent advice or support in Scotland, you can contact the Patient Advice and Support Service (PASS):

Tel: *<insert local PASS contact number(s)>* Email: *<insert local PASS email address>*

Website: *<insert PASS website>*

For independent advice or support in Northern Ireland, you can contact the Northern Ireland Public Services Ombudsman (NIPSO):

Tel: *<insert local NIPSO contact number(s)>* Email: *<insert local NIPSO email address>*

Website: *<insert NIPSO website>*

Contact details of the ABBRUPT Trial Office at BCTU:

Website: www.birmingham.ac.uk/ABBRUPT

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