**Add local headed letterhead**

ABBRUPT Trial: Comparing two current treatments for patients in ICU with new onset atrial fibrillation

(a heart condition)

# We would like to invite you to continue participating in the ABBRUPT trial

We are approaching you because you were admitted to the intensive care unit and were recruited into a research study that is being run at this hospital.

We would like to ask for your permission for you to continue to take part in this research study.

Before you make a decision, it is important that you understand why the research is being done and this information sheet tells you the purpose of the ABBRUPT trial, what has happened so far and what will happen if you agree to continue to take part.

Please take time to read the following information carefully and ask us if there is anything that is not clear or if you would like more information.

Please note: Continuing to taking part in this trial is entirely voluntary and will not affect your current or future NHS standard of care.



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ABBRUPT Trial

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# Trial Summary



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ABBRUPT Trial **2**

Whilst you were in the Intensive Care Unit (ICU), you were diagnosed with new onset atrial fibrillation (NOAF) and included in a clinical trial called ABBRUPT.

Patients admitted to ICU are at risk of developing atrial fibrillation (AF) for the first time. 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.

The ABBRUPT trial compares two of the effective and routinely used treatments for AF. However, clinicians do not yet know which treatment works best and ABBRUPT aims to discover which one (if any) works best.

The two treatments used are Amiodarone and Beta Blocker.

After you are discharged from the hospital, we will follow-up with you by telephone to see how you are.

Trial participation and information provided will be kept confidential and handled in accordance with the Data Protection Act 2018.

# Invitation

This information sheet is being provided to you because you have been included in a national clinical trial called ABBRUPT.

When you were admitted to the hospital you received the usual care from the hospital clinical care team. The clinical care team assessed your condition and found that you were suitable to take part in the ABBRUPT trial. Because you were very unwell, consent was taken from a person who represented you (your partner, relative, close friend, or a doctor independent to the ABBRUPT trial).

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 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 voluntary, and your decision will not affect your current or future NHS care.

If you choose to continue, you can stop being part of the trial at any time. We will keep and use the data collected up to the point of you stopping.

# What is the ABBRUPT trial and why is the study being conducted?



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ABBRUPT is a large scale national trial.

Each year approximately 10% of patients who are being treated in an ICU will develop AF which they did not have previously.

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 AF 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 these patients.

# What has happened so far?



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You were admitted to ICU because you were very unwell. Sometimes, when patients are very unwell, they will develop AF for the first time.

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.

You developed AF lasting for more than 30 minutes which required emergency treatment. You were therefore included in the ABBRUPT trial which is comparing two treatments for AF; Amiodarone (a drug used to prevent heart rhythm disorders) and Beta-Blockers (a group of drugs that make the heart beat slower and reduce blood pressure). Both medications are routinely used to treat AF and will have been given to you according to usual care guidelines.

Ordinarily, we would ask for your permission to include you in a trial before any research procedures take place, but because you were so unwell, we were unable to do this.

Following consultation with clinicians and carers with ‘lived experience’, it was determined that it would be in patients best interest to begin treatment first and then receive their consent later. We have special approval from a Research Ethics Committee to conduct emergency care research in this way.

The ABBRUPT Trial Team can obtain most of the information needed from your medical notes, which will have been recorded as part of routine care by your clinical care team. This information was entered into an online database, and the computer randomly allocated you to receive either standard treatment plus amiodarone or beta-blockers.

If you consent, a researcher from the ABBRUPT Trial Team will also take blood samples of 20ml (equivalent to a tablespoon) at four time points which will be used to undertake future ethically approved research in AF.

The blood samples will be labelled with your trial number and will be stored at the hospital where you are being treated for future analysis.

# What would continuing to take part involve?



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If you agree 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 your medical notes including the results of tests that are done as part of your usual care.

A researcher will monitor your progress for 90 days from when you first joined the study and will collect information on:

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

Following discharge from hospital, we will contact you at 60 days and at 90 days to ask you to tell us about your health status using an EQ5D-5L health questionnaire.

With your consent, your GP will be informed of your participation in the trial, but they do not have access to the trial data that we will collect.

# What if I change my mind?

The decision for you to continue in the study is entirely voluntary and you can change your mind at any time without having to give a reason.

If you do not want to continue to take part in the study, or change your mind at a later stage, this will not affect the care you receive from the NHS.

# What are the possible benefits of taking part?



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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 of taking part?

Both amiodarone and beta-blockers are widely used across the NHS. 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
* Eye Disorders
* Pain/ infection at the site of injection or drip Beta-blockers:
* Bradycardia
* Hypotension
* Dyspnoea (shortness of breath)
* Dizziness
* Headache
* Fatigue (feeling tired)
* Nausea (feeling sick)

The medical team that are caring for you have closely monitored your health and will continue to do so. If you have any concerns during your time 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?

Patient and public involvement has been integral to the development of the ABBRUPT trial.

A group consisting of patients and members of the public called the Clinical Research Ambassador Group (CRAG) helped to develop this research topic and the research questions that should be asked. CRAG members have vast experience in supporting clinical trials.

A member of this group is also a co-applicant of the funding grant and will continue to be involved in the trial.

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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 personal healthcare records or is able to influence your treatment

# Who has reviewed the study?



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All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your 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?



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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 at BCTU.

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 taking part in this study be kept confidential?



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All information collected about you 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.

The University of Birmingham (UoB) 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 are due to governance of the study, are duty bound to using it properly. Further information on data handling can be found on the privacy notice at [www.birmingham.ac.uk/abbrupt.](http://www.birmingham.ac.uk/abbrupt)

For this study, we will collect your name, gender, age, brief demographic data and medical history.

The only people allowed to have access to the information will be the researchers at the hospital and BCTU who are running the study and the regulatory authorities and sponsors who check that the study is being carried out correctly.

In all routine correspondence between the hospital and BCTU, we will identify you using your 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 you are will not be able to see your name or contact details. The only people at the University of Birmingham who will have access to information that identifies you, 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 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.

Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to know what information the ABBRUPT Trial Office has recorded about you. If you wish to view this information or find out more about how we use this information, please contact Legal Services at the address below.

Please note that a small fee may be payable to retrieve this information.

# What will happen to the trial data?



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All trial data will be retained for at least 25 years after the publication of the research outcomes.

Your trial data may be shared with other researchers to support related research in the future.

Your name contact details will be removed before doing so.

# 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 to 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 at the end of this Information Sheet.

# 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 you should continue to participate in the trial.

If the researcher is happy for you to continue in the trial, you will still have the option to decide whether you wish to continue. We may ask you to re-sign a consent form if you do.

If the researcher considers that you should stop (the reason will be explained to you) or if you decide not to carry on in the trial, the researcher will make arrangements for your usual care to continue.

# 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.

# Further information

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 PI name, job title>

<Insert tel and/or email> <Insert PI tel and/or email>

For independent advice or support in England and Wales, 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>

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>

Contact details of the ABBRUPT Trial Office at BCTU: Email: [abbrupt@trials.bham.ac.uk](mailto:abbrupt@trials.bham.ac.uk) Website: [www.birmingham.ac.uk/ABBRUPT](http://www.birmingham.ac.uk/ABBRUPT)

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The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.



Further information about this study can be found on the study website:

[**www.birmingham.ac.uk/ABBRUPT**](http://www.birmingham.ac.uk/ABBRUPT)

 