ISRCTN59775011 https://doi.org/10.1186/ISRCTN59775011

Investigating the clinical and cost-effectiveness of two different drugs (amiodarone and beta blockers) to treat patients with new-onset atrial fibrillation whilst in the intensive care unit

Submission date
14/09/2023

Recruitment status
Recruiting

Registration date
15/09/2023

Overall study status
Ongoing

Last Edited
15/09/2026

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Each year about 10% of patients who are being treated in an ICU will develop an irregular heartbeat which they did not have previously, called new-onset atrial fibrillation (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:
1. Normal body reactions to infection and injury
2. Altered levels of electrolytes (salts) in a patient's blood
3. The drugs used to support a patient's blood pressure
4. Certain commonly used ICU procedures
Some of the studies to look at the risks associated with AF suggest that patients who develop NOAF whilst in 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.

Who can participate?
Patients aged 16 years and over in an adult ICU who have developed NOAF

What does the study involve?
Participants will be randomly allocated to receive either amiodarone or beta-blockade. The choice of dose (and in the case of beta-blockade, the type) rests with the clinical team at site. Participants will be treated with the allocated intervention until sinus rhythm has been maintained for 24 hours. Clinicians should then consider stopping the intervention according to local practice. Both interventions can be administered by infusion/injection or orally.
Information will be collected from medical notes including the results of tests that are done as part of usual care. A researcher will monitor the patient's progress for 90 days from when they first joined the study and will collect information on:
1. The illness and treatment during their stay in ICU

2. The date the patient is discharged from ICU
3. The date the patient is discharged from hospital
4. How the patient feels around 60 days later (30-minute telephone call if discharged)
5. How the patient feels around 90 days later (30-minute telephone call if discharged)

What are the possible benefits and risks of participating?
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.

Where is the study run from?
The Birmingham Clinical Trials Unit (BCTU) coordinates the study at the University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
October 2022 to January 2030

Who is funding the study?
The National Institute for Health and Care Research, Health Technology Assessment (UK)

Who is the main contact?
abbrupt@trials.bham.ac.uk

Contact information

Type(s)
Scientific

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Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1007930

Central Portfolio Management System (CPMS)
57843

Protocol serial number
RG_22-153

Study information

Scientific Title
A randomised controlled trial to investigate the clinical and cost effectiveness of Amiodarone vs Beta Blockade for new-onset atrial fibRillation in icU - a Pragmatic sTudy (ABBRUPT)

Acronym
ABBRUPT

Study objectives
The ABBRUPT trial will assess the clinical and cost-effectiveness of two commonly used treatments for new-onset atrial fibrillation (NOAF) in patients in ICU to establish which management of AF is best to avoid harm and achieve optimal outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/10/2023, South Central - Oxford C (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; None provided; oxfordc.rec@hra.nhs.uk), ref: 23/SC/0334

Primary study design
Interventional

Study design
Multi-centre interventional randomized controlled open-label trial

Study type(s)
Efficacy, Quality of life, Treatment

Health condition(s) or problem(s) studied
New onset atrial fibrillation (NOAF)

Interventions
Patients will be randomised following confirmation of eligibility by a medically qualified doctor. They will be randomised to receive either amiodarone or beta-blockade. The choice of dose (and in the case of beta-blockade, the type) rests with the clinical team at site. Patients randomised to amiodarone will receive a loading dose (usually 300 mg over 1 hour) followed by a continuous infusion of (usually) between 300-1200 mg (usually 900 mg) per day with the treating clinician choosing the route of administration and duration. For those patients randomised to the control group, clinicians will be given the choice of beta-blocker: bisoprolol, metoprolol, esmolol, propranolol, 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. Patients will be treated with the allocated intervention until sinus rhythm has been maintained for 24 hours. Clinicians should then consider stopping the intervention according to local practice. All participants will be followed up for 90 days from randomisation.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Amiodarone, atenolol, bisoprolol, carvedilol, metoprolol tartrate, propranolol, Betaloc [metoprolol tartrate], esmolol, labetalol, Rapibloc [landiolol hydrochloride]

Primary outcome(s)
90-day mortality measured using patient records

Key secondary outcome(s)
1. ICU and hospital mortality measured up to day 90 using patient's medical notes
2. Rates of cardiovascular events including stroke, myocardial infarction or thromboembolism up to 90 days using patient's medical notes
3. Rate of established AF by the end of ICU stay/death/day 90 by using patient's medical notes
4. Number of episodes of bradycardia up to day 90 by using patient's medical notes
5. Number of bradycardia and bradycardic arrhythmias with haemodynamic compromise requiring intervention measured up to day 90 by using patient's medical notes
6. Number of significant hypotension episodes requiring intervention up to day 90 by using the patient's medical notes
7. Heart block measured up to day 90 by using patient's medical notes
8. Arrhythmia with haemodynamic compromise requiring intervention including DC cardioversion up to day 90 by using patient's medical notes
9. Cost-effectiveness of the interventions measured up to day 90 by using patient's medical notes
10. Healthcare resource use including ICU and hospital length of stay measured up to day 90 by using patient's medical notes

Completion date
31/01/2030

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 15/06/2026:

1. Adult Patients (age ≥16 years)
2. Monitored in an area of higher care with the ability to deliver the interventions
3. Onset of NOAF or a new episode of AF during the acute illness (A&E, deterioration on ward, after surgery) where there is a clinical indication to treat with amiodarone or beta blockers as determined by the attending clinician/ACCP or equivalent.
4. Usual electrolyte management with potassium and magnesium has taken place according to site practice

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Previous key inclusion criteria:

1. Patients in an adult ICU (age ≥16 years)
2. 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.
3. A minimum duration of AF of at least 30 minutes
4. Usual electrolyte management with potassium and magnesium according to site practice
5. A clinical indication to treat NOAF as determined by the attending clinician

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 15/06/2026:

1. Treatment with anticoagulants or antiarrhythmics for the treatment of AF before the current hospital admission *anticoagulants or antiarrhythmics used for any other purpose can be included
2. Current concomitant medication that are contraindicated with the intervention or comparator

medications (for example ciclosporin, itaconazole, letermovir)
3. Serum potassium of less than 4 mmol L-1 (measured either on point-of-care testing or laboratory)
4. Patients having undergone cardiac surgery during the current hospital admission, defined as any surgery including lung resections, 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
5. Thyrotoxicosis
6. Withdrawal of life support therapy within 24 hours
7. Any other known contraindication or known sensitivity to beta-blockers or amiodarone
8. Known pregnancy or patients currently known to be breast-feeding

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Previous key exclusion criteria:

1. Patients in receipt of amiodarone or a beta-blocker in the previous 24 hours
2. Patients receiving current concomitant medication with treatments that are contraindicated with the intervention/comparator medications
3. Patients with a serum potassium of <4 mmol L-1
4. Patients with a serum magnesium of <1.0 mmol L-1
5. 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
6. Patients with Thyrotoxicosis
7. Patients where there is a plan for withdrawal of life support therapy within 24 hours
8. Patients who have had other thoracic surgery that ingresses the thorax
9. Patients with any other known contraindication or known sensitivity to beta-blockers or amiodarone
10. Patients with a known pregnancy or patients currently known to be breastfeeding
11. Patients with any known previous documented history of AF, whether permanent, persistent or paroxysmal

Date of first enrolment
08/05/2024

Date of final enrolment
30/04/2029

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Lincoln County Hospital
Greetwell Road
Lincoln
England
LN2 5QY

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
England
NW3 2QG

Study participating centre
St Georges Hospital
Blackshaw Road
Tooting
London
England
SW17 0QT

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
England
TA1 5DA

Study participating centre
Pinderfields Hospitals NHS Trust
Trust Hq, Rowan House
Pinderfields General Hospital
Aberford Road
Wakefield
England
WF1 4EE

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

Study participating centre
Watford General Hospital
60 Vicarage Road
Watford
England
WD18 0HB

Study participating centre
Bedford Hospital
Icash Bedford Hospital
Kempston Road
Bedford
England
MK42 9DJ

Study participating centre
Blackburn Royal Infirmary
Infirmary Road
Blackburn
England
BB2 3LR

Study participating centre
Blackpool Teaching Hospitals NHS Foundation Trust
Victoria Hospital
Whinney Heys Road
Blackpool
England
FY3 8NR

Study participating centre
Royal Bournemouth Hospital
Castle Lane East

Bournemouth
England
BH7 7DW

Study participating centre
Poole
Poole Hospital
Longfleet Road
Poole
England
BH15 2JB

Study participating centre
Bolton NHS Foundation Trust
The Royal Bolton Hospital
Minerva Road
Farnworth
Bolton
England
BL4 0JR

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
England
BD9 6RJ

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road

Hull
England
HU3 2JZ

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Road
Calow
Chesterfield
England
S44 5BL

Study participating centre
Darlington Memorial Hospital NHS Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
England
DL3 6HX

Study participating centre
Forth Valley Royal Hospital
Stirling Road
Larbert
Scotland
FK5 4WR

Study participating centre
Glan Clwd Hospital
Ysbyty Glan Clwydd
Bodelwyddan
Rhyl
Wales
LL18 5UJ

Study participating centre
Birmingham Heartlands NHS Trust
Bordesley Green East
Birmingham
England
B9 5SS

Study participating centre
Good Hope Hospital
Rectory Road
Sutton Coldfield
England
B75 7RR

Study participating centre
Hereford County Hospital
Stonebow Road
Hereford
England
HR1 2BN

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
Kettering General Hospital Laboratory
Kettering General Hospital
Rothwell Road
Kettering
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NN16 8UZ

Study participating centre
Kings College Hospital
Denmark Hill
London
England
SE5 9RS

Study participating centre

Salford Royal Hospital
Stott Lane
Eccles
Salford
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M6 8HD

Study participating centre
Northern Care Alliance NHS Foundation Trust
Mayo Building
Salford Royal
Stott Lane
Salford
England
M6 8HD

Study participating centre
The Walton Centre NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool
England
L9 7LJ

Study participating centre
Basildon
Basildon Hospital
Nethermayne
Basildon
England
SS16 5NL

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
England
BA1 3NG

Study participating centre

United Leeds Teaching Hospitals NHS Trust
Trust Offices
Leeds General Infirmary
Great George Street
Leeds
England
LS1 3EX

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
Leighton Hospital
Leighton
Crewe
England
CW1 4QJ

Study participating centre
Luton & Dunstable Hospital
Lewsey Road
Luton
England
LU4 0DZ

Study participating centre
Milton Keynes Urgent Care Services Cic
Milton Keynes General Hospital
Standing Way
Eaglestone
Milton Keynes
England
MK6 5NG

Study participating centre

Portsmouth Hospitals University NHS Trust
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
England
PO6 3LY

Study participating centre
Rotherham General Hospital Laboratory
Rotherham General Hospital
Oakwood
Moorgate Road
Rotherham
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S60 2UD

Study participating centre
Royal Hampshire County Hospital
Romsey Road
Winchester
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SO22 5DG

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
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RG24 9NA

Study participating centre
Royal Liverpool University Hospital NHS Trust
Royal Liverpool University Hospital
Prescot Street
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L7 8XP

Study participating centre

Sandwell General Hospital Laboratory
Sandwell General Hospital
Lyndon
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B71 4HJ

Study participating centre
Southampton
Southampton General Hospital
Tremona Road
Southampton
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SO16 6YD

Study participating centre
Torbay and South Devon NHS Foundation Trust
Torbay Hospital
Newton Road
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TQ2 7AA

Study participating centre
University College London Hospital
250 Euston Road
London
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Study participating centre
University Hospital Birmingham
Queen Elizabeth Hospital
Edgbaston
Birmingham
England
B15 2TH

Study participating centre
Warrington and Halton Teaching Hospitals NHS Foundation Trust
Warrington Hospital

Lovely Lane
Warrington
England
WA5 1QG

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the BCTU Data Sharing Committee following a formal Data Sharing Agreement (if applicable) email: abbrupt@trials.bham.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	11/10/2023	10/05/2024	No	No
Protocol file	version 4.0	20/01/2025	17/06/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes