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	Recruitment status Recruiting	[X] Prospectively registered		
14/09/2023		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/09/2023	Ongoing Condition category	Results		
Last Edited		Individual participant data		
18/06/2025	Circulatory System	[X] Record updated in last yea		

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 December 2026

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

Contact name

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Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1007930

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

RG_22-153, IRAS 1007930, CPMS 57843

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

Study design

Multi-centre interventional randomized controlled open-label trial

Primary study design

Interventional

Study type(s)

Quality of life, Treatment, Efficacy

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

Eligibility

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

Adult

Lower age limit

16 years

Sex

All

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

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre Lincoln County Hospital Greetwell Road

Lincoln
United Kingdom
LN2 5QY

Study participating centre Royal Free London NHS Foundation Trust

Royal Free Hospital Pond Street London United Kingdom NW3 2QG

Study participating centre St Georges Hospital

Blackshaw Road Tooting London United Kingdom SW17 0QT

Study participating centre Musgrove Park Hospital (taunton)

Musgrove Park Hospital

Taunton United Kingdom TA1 5DA

Study participating centre Pinderfields Hospitals NHS Trust

Trust Hq, Rowan House Pinderfields General Hospital Aberford Road Wakefield United Kingdom WF1 4EE

Study participating centre Sunderland Royal Hospital

Kayll Road Sunderland United Kingdom SR4 7TP

Study participating centre Watford General Hospital

60 Vicarage Road Watford United Kingdom WD18 0HB

Study participating centre Bedford Hospital

Icash Bedford Hospital Kempston Road Bedford United Kingdom MK42 9DJ

Study participating centre Blackburn Royal Infirmary

Infirmary Road Blackburn United Kingdom BB2 3LR

Study participating centre Blackpool Teaching Hospitals NHS Foundation Trust

Victoria Hospital Whinney Heys Road Blackpool United Kingdom FY3 8NR

Study participating centre Royal Bournemouth Hospital

Castle Lane East Bournemouth United Kingdom BH7 7DW

Study participating centre

Poole

Poole Hospital Longfleet Road Poole United Kingdom BH15 2JB

Study participating centre Bolton NHS Foundation Trust

The Royal Bolton Hospital Minerva Road Farnworth Bolton United Kingdom BL4 0JR

Study participating centre Bradford Teaching Hospitals NHS Foundation Trust

Bradford Royal Infirmary Duckworth Lane Bradford United Kingdom BD9 6RJ

Study participating centre Southmead Hospital

Southmead Road Westbury-on-trym Bristol United Kingdom BS10 5NB

Study participating centre Hull University Teaching Hospitals NHS Trust

Hull Royal Infirmary Anlaby Road Hull United Kingdom HU3 2JZ

Study participating centre Chesterfield Royal Hospital NHS Foundation Trust

Chesterfield Road Calow Chesterfield United Kingdom S44 5BL

Study participating centre Darlington Memorial Hospital NHS Trust

Darlington Memorial Hospital Hollyhurst Road Darlington United Kingdom DL3 6HX

Study participating centre Forth Valley Royal Hospital

Stirling Road Larbert United Kingdom FK5 4WR

Glan Clwd Hospital

Ysbyty Glan Clwydd Bodelwyddan Rhyl United Kingdom LL18 5UJ

Study participating centre Birmingham Heartlands NHS Trust

Bordesley Green East Birmingham United Kingdom B9 5SS

Study participating centre Good Hope Hospital

Rectory Road Sutton Coldfield United Kingdom B75 7RR

Study participating centre Hereford County Hospital

Stonebow Road Hereford United Kingdom HR1 2BN

Study participating centre The James Cook University Hospital

Marton Road Middlesbrough United Kingdom TS4 3BW

Study participating centre Kettering General Hospital Laboratory

Kettering General Hospital Rothwell Road Kettering United Kingdom NN16 8UZ

Study participating centre Kings College Hospital

Denmark Hill London United Kingdom SE5 9RS

Study participating centre Salford Royal Hospital

Stott Lane Eccles Salford United Kingdom M6 8HD

Study participating centre Northern Care Alliance NHS Foundation Trust

Mayo Building Salford Royal Stott Lane Salford United Kingdom M6 8HD

Study participating centre The Walton Centre NHS Foundation Trust

Lower Lane Fazakerley Liverpool United Kingdom L9 7LJ

Study participating centre Basildon

Basildon Hospital Nethermayne Basildon United Kingdom SS16 5NL

Study participating centre Royal United Hospitals Bath NHS Foundation Trust

Combe Park Bath United Kingdom BA1 3NG

Study participating centre United Leeds Teaching Hospitals NHS Trust

Trust Offices
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary Infirmary Square Leicester United Kingdom LE1 5WW

Study participating centre Leighton Hospital

Leighton Crewe United Kingdom CW1 4QJ

Study participating centre Luton & Dunstable Hospital

Lewsey Road Luton United Kingdom LU4 0DZ

Study participating centre Milton Keynes Urgent Care Services Cic

Milton Keynes General Hospital Standing Way Eaglestone Milton Keynes United Kingdom MK6 5NG

Study participating centre Portsmouth Hospitals University NHS Trust

Queen Alexandra Hospital Southwick Hill Road Cosham Portsmouth United Kingdom PO6 3LY

Study participating centre Rotherham General Hospital Laboratory

Rotherham General Hospital Oakwood Moorgate Road Rotherham United Kingdom S60 2UD

Study participating centre Royal Hampshire County Hospital

Romsey Road Winchester United Kingdom SO22 5DG

Study participating centre Basingstoke and North Hampshire Hospital

Aldermaston Road Basingstoke United Kingdom RG24 9NA

Study participating centre Royal Liverpool University Hospital NHS Trust

Royal Liverpool University Hospital Prescot Street Liverpool United Kingdom L7 8XP

Study participating centre Sandwell General Hospital Laboratory

Sandwell General Hospital Lyndon West Bromwich United Kingdom B71 4HJ

Study participating centre Southampton

Southampton General Hospital Tremona Road Southampton United Kingdom SO16 6YD

Study participating centre Torbay and South Devon NHS Foundation Trust

Torbay Hospital Newton Road Torquay United Kingdom TQ2 7AA

Study participating centre University College London Hospital

250 Euston Road London United Kingdom NW1 2PG

Study participating centre

University Hospital Birmingham

Queen Elizabeth Hospital Edgbaston Birmingham United Kingdom B15 2TH

Study participating centre Warrington and Halton Teaching Hospitals NHS Foundation Trust

Warrington Hospital Lovely Lane Warrington United Kingdom 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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
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