

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

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| Submission date 14/09/2023 | Recruitment status Recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 15/09/2023 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 18/06/2025 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 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)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1007930

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

31/12/2026

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

30/06/2026

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

Study participating centre

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
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PO6 3LY

Study participating centre
Rotherham General Hospital Laboratory
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Oakwood
Moorgate Road
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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
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

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 |