ISRCTN13252515 https://doi.org/10.1186/ISRCTN13252515

A review and analysis of treatments for irregular heart rhythm

Submission date
04/02/2019

Recruitment status
No longer recruiting

Registration date
11/02/2019

Overall study status
Completed

Last Edited
06/03/2024

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 18/10/2019:
Background and study aims
Atrial fibrillation is a heart problem that causes an irregular heartbeat. It can cause the heart to beat more rapidly and reduce the heart's ability to pump blood around the body efficiently. It also increases the risk of blood clots forming inside the heart. These clots may then be pumped out of the heart, through the blood vessels, to other parts of the body. This causes strokes if they spread to the brain.
Atrial fibrillation is a common problem in patients outside intensive care units (ICUs). Good, evidence-based, guidelines exist to help doctors treat people who develop this condition.
Around 10% of people treated on an ICU develop atrial fibrillation as a complication of their severe underlying illness. This additional problem makes them more unstable so they stay longer in the ICU and are more likely to die. Atrial fibrillation therefore needs prompt and effective treatment to prevent further harm.
Treatments for atrial fibrillation that work in people who are otherwise well may not work in people who are already very ill before their heart changes rhythm. This means that guidelines for treating atrial fibrillation outside ICU are not helpful for patients treated on an ICU. There is uncertainty about the best treatment, and practices differ between countries and between different ICUs in the same country.
People who have atrial fibrillation outside an ICU are often given medications such as warfarin (commonly referred to as a "blood-thinner") to reduce their risk of stroke. However these medications can cause bleeding. Risk scoring systems are used to help doctors balance the risk of bleeding against the risk of stroke but these scoring systems may not work for patients admitted to ICUs. This is because their risk of bleeding is higher and their risk of stroke is not well understood.
Our research will bring together the best evidence on which to base improved guidelines for the treatment of patients who develop atrial fibrillation on an ICU. We will start with a review of all published research and expert opinions. This is called a scoping review. It will also suggest the best areas for future research.

Who can participate?
With permission, we will use databases of medical records of patients treated on ICUs to investigate the benefits and harms of existing treatments for atrial fibrillation. Using existing

data is a cost-efficient way to work out which treatments need more detailed investigation.
We will use two databases, PICRAM and MIMIC-III, to see which treatments appear to work best for atrial fibrillation. PICRAM is a large detailed research database of patients admitted to three ICUs in the UK. It includes information about 13,000 patients. MIMIC-III holds similar data on 52,000 patients from the ICUs of one large US hospital. Many treatments are different in the two countries, including treatment for atrial fibrillation.
The NIHR HIC critical care database holds some of the clinical details on 40,000 patients from five UK ICUs. We will use this to check some of our findings.

What does the study involve?
To understand how we could improve outcomes for patients who develop atrial fibrillation on an ICU by thinning their blood, we need to know how frequently strokes occur, both in hospital and after they go home. We will use the RISK-II database of over 900,000 patients treated on 200 ICUs in England to estimate how many patients suffered a stroke in hospital and after discharge.

What are the possible benefits and risks of participating?
Not applicable

Where is the study run from?
University of Oxford, Kadoorie Centre for Critical Care Research & Education, Level 3 John Radcliffe Hospital, Headley Way, Headington, Oxford, OX3 9DU, UK

When is the study starting and how long is it expected to run for?
February 2019 to November 2020

Who is funding the study?
National Institute for Health Research Health Technology Assessment

Who is the main contact?
Rachel Henning, ccrg@ndcn.ox.ac.uk

Previous plain English summary:
Background and study aims
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When is the study starting and how long is it expected to run for?
February 2019 to August 2020

Who is funding the study?
National Institute for Health Research Health Technology Assessment

Who is the main contact?
Julie Darbyshire, julie.darbyshire@ndcn.ox.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Rachel Henning

Contact details

Kadoorie Centre for Critical Care Research and Education
Level 3, John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 223101
ccrg@ndcn.ox.ac.uk

Type(s)
Scientific

Contact name
Dr Peter Watkinson

Contact details
University of Oxford Critical Care Research Group,
Nuffield Department for Clinical Neurosciences,
Kadoorie Centre for Critical Care Research & Education,
Level 3, John Radcliffe Hospital
Headley Way, Headington
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 223101
ccrg@ndcn.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Critical Care Atrial Fibrillation Evaluation: a scoping review and data base analysis

Acronym
CAFE

Study objectives
Scoping review
1. To evaluate the evidence for the effectiveness and safety of:

a. pharmacological and non-pharmacological (electrical, electrolyte, fluid) New-onset atrial fibrillation (NOAF) treatments; and
b. acute anticoagulation

2. To provide guidance for the database analysis on:
a. NOAF definitions used in patients on an ICU;
b. patient subgroups who develop NOAF on an ICU; and
c. inclusion/exclusion of specific treatments and potential confounders.

3. To determine barriers to future research.

Database analysis
1. To compare the use and effectiveness of pharmacological and non-pharmacological NOAF treatments with respect to heart rate and rhythm control.
2. To assess anticoagulation use, effect on thromboembolic complications and safety.
3. To determine the incidence of short and long-term complications of NOAF and identified treatments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/07/2019, Committee on Clinical Investigations (Beth Israel Deaconess Medical Center, 330 Brookline Ave., Boston, MA 02215, USA; +1 617-975-8511, alisbon@bidmc.harvard.edu), ref: 2001P001699

Study design
Two phase project. Phase 1: scoping review; Phase 2: retrospective database analysis

Primary study design
Other

Study type(s)
Other

Health condition(s) or problem(s) studied
Patients who experience new onset atrial fibrillation (NOAF) during their admission for intensive care

Interventions
None - retrospective data analysis & review of literature only

Intervention Type
Other

Primary outcome(s)
To evaluate the evidence for the effectiveness and safety of treatment for new onset atrial fibrillation (NOAF) in the intensive care unit

Key secondary outcome(s))

1. To assess anticoagulation use and their effect on thromboembolic complications and safety
2. To determine the incidence of short and long-term complications of NOAF and identified treatments
3. To determine barriers to future research in the field

Completion date
30/11/2020

Eligibility

Key inclusion criteria
To be included in the retrospective data analysis phase of the project patients must have been admitted to one of the intensive care units included in the PICRAM & MIMIC-III datasets

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
759964

Key exclusion criteria
1. Patients with known prior AF
2. Patients (and studies for the scoping review) with evidence of NOAF outside of the intensive care unit

Date of first enrolment
01/04/2019

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
United Kingdom

England

United States of America

Study participating centre
University of Oxford
Kadoorie Centre for Critical Care Research & Education,
Level 3 John Radcliffe Hospital,
Headley Way, Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
ICNARC
Napier House,
24 High Holborn
London
United Kingdom
WC1V 6AZ

Study participating centre
University of York
Centre for Reviews and Dissemination,
University of York
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name

National Institute for Health 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 are available from the corresponding author (ccrg@ndcn.ox.ac.uk) on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Effectiveness of treatments	16/11/2021	13/01/2022	Yes	No
Results article	Epidemiology and outcomes	06/07/2022	08/07/2022	Yes	No
Results article		01/11/2021	06/03/2024	Yes	No
Other publications	Literature review	21/07/2021	02/09/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.1	20/02/2019	18/08/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes