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Screening for atrial fibrillation with ECG to reduce stroke

Submission date
25/01/2019

Recruitment status
No longer recruiting

Registration date
29/01/2019

Overall study status
Completed

Last Edited
16/05/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Atrial fibrillation (AF) is a heart condition that causes irregular heartbeat. It affects up to 1 in 10 people over the age of 65. Atrial fibrillation greatly increases risk of stroke, but treatment with blood thinning ("anticoagulant") medication can stop this happening. About 10% of strokes happen in people unaware they have atrial fibrillation. Detecting atrial fibrillation can be difficult because it often comes and goes, and may not cause symptoms.

Many clinicians think the NHS should promote atrial fibrillation screening. The UK National Screening Committee has highlighted a lack of evidence that detecting atrial fibrillation in people by screening would benefit them.

We are therefore undertaking a large 8-year programme of work to find out if screening for atrial fibrillation in people aged 65 and over does prevent stroke and other problems like heart attacks, does not cause significant harm, and represents good value-for-money for the NHS. The SAFER Study is a feasibility study to inform the development of what will be the world's largest atrial fibrillation screening trial that will address these questions.

The SAFER Study will take place in 12 GP practices in East England who will invite about 9,600 patients to take part.

Some consented participants will be invited to be screened for atrial fibrillation. Participants will use a handheld single-lead ECG recorder to record ECGs at home over a period of 2-4 weeks. The ECGs will be read by a validated computer algorithm, with diagnoses confirmed by a cardiologist. Participants diagnosed with atrial fibrillation will be invited to a GP appointment to discuss treatment with blood thinning (anticoagulant) medication.

As part of this study we will conduct focus groups and interviews with participants to explore their views and beliefs about screening, atrial fibrillation, and their experience of being screened. We will also conduct interviews with GP practice staff to understand the practice experience of screening for atrial fibrillation.

Background and study aims
Atrial fibrillation (AF) is a heart condition that causes an irregular heartbeat. It affects up to 1 in

10 people over the age of 65, but does not necessarily cause symptoms. Having atrial fibrillation increases the risk of having a stroke 5-fold, but treatment with medication can significantly lower this risk as well as lowering your risk of having a heart attack. The aim of this study is to find out whether screening people over the age of 65 years for atrial fibrillation and treating them with medication:
1. is feasible in GP practices
2. prevents the number of strokes we think it will; and
3. is good value for money for the NHS
The results from this feasibility study will inform the design of a large trial to help the NHS decide whether to start a national screening programme for atrial fibrillation to prevent strokes.

Who can participate?
Men and women aged 65 and over, not on long-term anticoagulation medication, not on the palliative care register and not living in a nursing or care home.

What does the study involve?
Participants consent to give permission for specific information from medical records to be shared with the research team at various points over the next few years. This information is collected from GP practice records and from other health-related records. The kind of information collected included medications, use of healthcare services and stroke and cardiovascular disease related factors (for example weight, age, blood pressure, other medical conditions, and how well their kidneys and liver are working). Participants do not need to do anything to provide this information. Some participants may be invited to be screened for atrial fibrillation at their GP practice. Screening involves simply holding a small, safe, non-invasive recording device for 30 seconds at a time. Not everyone is invited to a screening appointment and, if a participant is, they are under no obligation to attend. On a couple of occasions participants may also receive a questionnaire to complete and return in a Freepost envelope (or complete online). Participants are under no obligation to complete this questionnaire. Some participants may be invited to take part in other studies related to atrial fibrillation and/or screening. Further information about what these would involve is sent. Participants are free to decide at that point whether or not they want to do them.

What are the possible benefits and risks of participating?
There may not be any direct benefit to participants for taking part. However, they may find it rewarding to know that they are contributing to research that aims to prevent stroke and heart attacks in people in the future. Some may receive a diagnosis of AF and therefore be given the opportunity to lower their greater risk of a stroke. Identifiable medical data from practices will be shared with the study team. All data collection, storage and handling processes will comply with the relevant security policies and regulations. Every effort will be made to ensure the security and confidentiality of participants' data.

Where is the study run from?
University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
October 2018 to December 2023

Who is funding the study?
The NIHR School for Primary Care Research and the NIHR Programme Grant for Applied Research (UK)

Who is the main contact?
Andrew Dymond
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Study website
www.safer.phpc.cam.ac.uk/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18/LO/2066

Study information

Scientific Title
Screening for Atrial Fibrillation with ECG to Reduce stroke (SAFER) - a feasibility study

Acronym
SAFER

Study objectives

This is the development and feasibility work to inform the intervention design, measures of psychological outcome and the feasibility of a screening programme for atrial fibrillation (AF) in primary care. These will inform a subsequent large cluster randomised controlled trial. The aim is to:
1. Determine how long and how often people should be screened to see if they have paroxysmal AF
2. Determine the practice experience of AF screening
3. Explore patient attitudes to and experiences of AF screening
4. Determine how best to measure the psychological effects on patients of screening for AF
5. Determine if screening for AF (including paroxysmal AF) is feasible in general practice in people aged 65 and over using a hand-held electrocardiogram (ECG) recorder (supplied by Zenicor)
6. Develop a process of audit, feedback and quality assurance of screening to inform our fidelity assurance in the subsequent trial
7. Finalise target population age range for the cluster randomised trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Central Research Ethics Committee, London - Central Research Ethics Committee, 3rd Floor, Barlow House, 4 Minshull Street, Manchester,
M1 3DZ, Tel: +44 (0)207 1048 007, Email: NRESCommittee.London-Central@nhs.net, 20/12 /2018, REC ref: 18/LO/2066

Study design
Multicentre non-randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
Not currently available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
Patients will be invited to join the SAFER Study with a Participant Information Sheet and Informed Consent Form from their GP surgery. Consent will be given by returning the consent form or by completed the online consent form. This consent confirms that the participant is

happy for the research team to access their medical records and to follow them up via electronic health registries. Some participants will, subsequently, be invited to attend a screening appointment at their local GP surgery.

The screening appointment will be led by a nurse/HCA and involve having a single lead ECG using a handheld Zenicor device (provided to the surgery, for the purposes of the study only, by the study team). Participants will be provided with instructions on how to use the device by the nurse/HCA and asked to take the device home and record 2-4 ECGs per day for 2-4 weeks.

On completion of the screening period, and once the device has been returned to the GP surgery by the participant, the ECGs will be reviewed by a study team nurse and cardiologist (if necessary). All results will be fed back to the GP, with the expectation that those participants identified as having atrial fibrillation are invited by the GP surgery for an appointment to discuss medication in order to reduce their increased risk of stroke.

Intervention Type
Procedure/Surgery

Primary outcome measure
As this is a feasibility study with a large qualitative component, there are a number of outcome measures that are considered primary:
1. Incremental increase in new AF detection rate by number of days screened and by number of times screened per day; measured using a handheld single-lead ECG device (Zenicor) at baseline
2. New AF detection rate, measured using a handheld single-lead ECG device (Zenicor) at baseline
3. % of new AF detected that is persistent versus paroxysmal; measured using a handheld single-lead ECG device (Zenicor) at baseline
4. % of patients with an AF code on the GP record who have confirmed AF from the screening process; measuredusing a handheld single-lead ECG device (Zenicor) at baseline
5. % eligible patients who consent – estimated to be around 50%; measured at baseline
6. % people who consent who are screened in six months – estimated to be around 40% over six months; measured at baseline
7. % people screened who have 2-week paroxysmal AF screening; measured using a handheld single-lead ECG device (Zenicor) at baseline
8. % people whose paroxysmal AF screening includes at least 15 ECG traces; measured using a handheld single-lead ECG device (Zenicor) at baseline
9. % people who have AF identified (subdivided by new/previously known; paroxysmal/ permanent); measured using a handheld single-lead ECG device (Zenicor) and compared to previous medical notes at baseline
10. % people who have AF identified who are reviewed by their GP; measured post-screening
11. % people with AF commenced on anticoagulation (sub-divided by new/previously known; CHA2DS2-Vasc score: 1 or ≥1); measured post screening
12. % completeness of baseline data from electronic record; measured post screening
13. All of the above criteria in age sub-groups to refine age entry criteria to the internal pilot, measured after data collection.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/10/2018

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Age ≥ 65 years (patients)
2. Gender: both males and females

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
4,800

Key exclusion criteria
1. Long-term anticoagulation therapy for stroke prevention.
2. On the palliative care register.
3. Resident in a nursing home.

Date of first enrolment
01/02/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Cambridge
Department of Public Health and Primary Care: Primary Care Unit
Strangeways Research Laboratory
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Sponsor information

Organisation
University of Cambridge

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Sponsor type
University/education

Website
http://www.cam.ac.uk/

ROR
https://ror.org/013meh722

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust

Sponsor details
RMG Office
Lockton House
Clarendon
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United Kingdom
CB2 8FH
+44 (0)1223 725466
v.shaw@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.cpft.nhs.uk/

ROR

https://ror.org/040ch0e11

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

Publication and dissemination plan
The protocol is yet to be published but will be prior to the results. Planned publication of the results in a high-impact peer reviewed journal.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
Requests for pseudonymised data should be directed to the study co-ordinator (Andrew Dymond using SAFER@medschl.cam.ac.uk) and will be considered by the investigators, in accordance with participant consent.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	Qualitative results	16/03/2022	18/03/2022	Yes	No

Interim results article	How to embed qualitative research in trials: insights from the feasibility study of the SAFER trial programme	12/05/2022	16/05/2022	Yes	No
HRA research summary			28/06/2023	No	No