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Screening for atrial fibrillation using economical and accurate technology

Submission date 29/06/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/08/2016	**Overall study status** Completed	
Last Edited 23/03/2020	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is a common heart condition, affecting millions of people worldwide. The heart consists of two upper chambers (atria) and two lower chambers (ventricles). Inside the right atrium, a cluster of cells (sinus node) are responsible for firing electrical signals into the heart muscle causing the heart to beat regularly (sinus rhythm). When a person is suffering from AF, the normal signals from the sinus node do not work properly, causing other parts of the atria to fire chaotically. These uncoordinated signals cause the heart to beat irregularly and often very fast (arrhythmia). People with AF have a significantly higher risk of having a stroke, and so it is important to accurately diagnose it as soon as possible. At the moment there is no UK screening programme for AF. Several relatively low cost devices with good accuracy now exist which can be used to pick up AF. These measure the electrical heart trace or pulse over short time periods (less than a few minutes) and can also be used in GP surgeries to screen for AF. The aim of this study is to test the accuracy of four different devices (a blood pressure meter, a hand-held device, a heart rate monitor belt and a wearable heartbeat recording device) by comparing them to the current best way of detecting AF (gold standard), a 12-lead ECG. The study also aims to find out how people feel about using the devices, in terms of comfort and ease of use.

Who can participate?
Adults aged 65 and over who are able to read and speak English.

What does the study involve?
Participants attend a single appointment at their GP surgery, during which a nurse performs the screening tests using the devices in a random order (this should take a couple of minutes per device). The devices are non-invasive (they fit on the skin): one device uses the pulses detected while a blood pressure reading is taken; the second device records an electrical trace of the heart by simply holding the device with the fingertips; the third device uses a heart rate monitor belt (used by athletes) that straps comfortably to the chest to obtain electrical pulse signals; and the fourth device also attaches to the chest using two gel electrodes (sticky pads which conduct electricity). Participants then go on to have a standard ECG test, in which 12 electrodes are attached to the body to measure the electrical activity of the heart. The results of this test are

then interpreted by a panel of cardiologists (heart doctors). Participants are then asked to rate the devices for comfort and ease of use. The accuracy of each of the devices is determined by comparing the results of each test to the ECG (which is the best known way of detecting AF).

What are the possible benefits and risks of participating?
Participants who are found to have AF benefit from being given this information so that they can be treated. There are no notable risks involved with participating. Although in rare cases, some participants may have some minor skin irritation after having an ECG taken (caused by the electrode gel).

Where is the study run from?
Highfield Health, Southampton (UK)

When is the study starting and how long is it expected to run for?
November 2011 to May 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Screening for Atrial Fibrillation using Economical and Accurate TechnologY (SAFETY) – a pilot study

Acronym
SAFETY

Study objectives
The aim of this study to assess the accuracy of a novel algorithm using a Bluetooth heart rate monitor belt and a wearable heart rate monitor to detect Atrial Fibrillation compared with a standard 12-Lead ECG. The accuracy will be compared to two existing devices: WatchBP (a blood pressure meter) and AliveCor (ahand-held ECG device).

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City & East REC, 30/06/2016, ref: 16/LO/1173

Study design
Diagnostic accuracy case-control study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
Each participant will attend their GP surgery for one visit. Each participant will be tested using 4 devices in random sequence, followed by a standard 12 lead ECG. Each test is performed immediately after the preceding test, with no wash out period in between.

AliveCor: This involves the participant to hold fingers on electrodes for 30s while a single lead ECG trace is obtained.
WatchBP: This involves a blood pressure measurement to be taken (automated) just like any other blood pressure measurement.
Polar Heart rate monitor belt: This involves wearing a polar heart rate monitor belt which will obtain heartbeat intervals which will be used by a smartphone app.
FirstbeatBodyguard2: This involves having two gel-electrodes placed on the chest and have the firstbeat bodyguard2 device attached which will record heartbeat intervals for a few minutes.

Participants then undergo a standard 12 lead ECG, the result of which is read by a panel of cardiologists. The diagnostic accuracy of each device is then determined through comparison with the results of the 12 lead ECG.

Intervention Type
Device

Primary outcome(s)
Diagnostic accuracy of WatchBP, AliveCor, Polar heart rate monitor belt (with diagnostic algorithm), Firstbeat Bodyguard2 (with diagnostic algorithm) are determined through comparison with the 12-lead ECG reference test at the study visit.

Key secondary outcome(s))
1. Comfort is measured using a visual analogue scale immediately after all tests are completed
2. Ease of use for each device is measured using a visual analogue scale immediately after all tests are completed

Completion date
31/12/2017

Eligibility

Key inclusion criteria
AF Participants:
1. Aged 65 years an over
2. Coded as AF on their GP records

Control participants:
1. Aged 65 years an over
2. No known AF

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
418

Key exclusion criteria
All participants:
1. Aged under 65
2. Permanent pacemaker in situ
3. Dementia / lacking in capacity
4. Previous moderate or severe skin reaction to electrode gel

Date of first enrolment
01/09/2016

Date of final enrolment

31/08/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Highfield Health
31 University Road
Southampton
United Kingdom
SO171BJ

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

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

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/10/2018	23/08/2019	Yes	No
Protocol article	protocol	13/01/2017		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	qualitative study	18/03/2020	23/03/2020	Yes	No
Participant information sheet	version V2	29/06/2016	10/08/2016	No	Yes