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Assessment of remote heart rhythm sampling using the AliveCor® heart monitor to screen for atrial fibrillation

Submission date
07/04/2015

Recruitment status
No longer recruiting

Registration date
09/07/2015

Overall study status
Completed

Last Edited
17/08/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Atrial Fibrillation (AF) is a heart condition that causes an irregular and often abnormally fast heart rate (arrhythmia). A normal heart rate should be between 60 and 100 beats a minute when you're resting, and is regular, but in AF the heart rate may be over 140 beats a minute. AF may lead to a number of problems, including dizziness and shortness of breath. AF is the most common type of arrhythmia and is linked to an increased risk of stroke. This is often treated with blood thinning medication which reduces the risk of stroke by 70%. Episodes of AF can have no symptoms (asymptomatic) making it very hard to diagnose, however the risk of stroke remains the same. There is a need for easy and cost-effective ways to diagnose asymptomatic AF. The AliveCor® is an electrocardiogram (ECG) heart rhythm monitor, and is a simple way for patients to monitor and quickly interpret their own heart rhythm. The aim of this study is to test whether the AliveCor® system can be used to identify patients with AF in the community so as to help earlier diagnosis and to reduce the incidence of major cardiovascular events such as stroke.

Who can participate?
Patients 65 years+ diagnosed with various risk factors associated with AF.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) use the AliveCor® heart rhythm monitor and are asked to submit an ECG tracing twice a week for 12 months. Participants may be asked to attend the clinic based on their ECG results. Those in group 2 (control group) are given standard primary care. Information related to participants' health, such as cardiac events or occurrence of stroke, is collected during the 12-month study period using data from GP and hospital appointments. Both groups have telephone contact at week 12 and 32.

What are the possible benefits and risks of participating?
A benefit of taking part in this study is that the results could impact upon the incidence of stroke by allowing earlier detection of AF and better outpatient treatment to prevent stroke.

Where is the study run from?
Swansea University (UK)

When is the study starting and how long is it expected to run for?
April 2014 to December 2016

Who is funding the study?
1. Telehealth Grant - Welsh Assembly Government (UK)
2. AliveCor, Inc (USA)

Who is the main contact?
Ms L Bastin (UK)

Contact information

Type(s)
Public

Contact name
Ms Lisa Bastin

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
JCRF 869

Study information

Scientific Title
Assessment of remote heart rhythm sampling using AliveCor® to screen an at risk population of atrial fibrillation: a randomised controlled trial

Study objectives
To determine whether use of the AliveCor® heart rhythm monitor by patients at increased risk of developing atrial fibrillation is able to increase the number of patients diagnosed with this

abnormal heart rhythm compared with routine care over a 12 month period. Primary care work has looked at the utility of random opportunistic pulse checks to identify possible patients with AF, which has been shown to be a cost effective way of identifying AF. This paradigm requires attendance to primary care, a subsequent ElectroCardioGram (ECG) to be performed and an accurate interpretation of the ECG trace. It remains a one off check. The AliveCor monitoring system provides a simple means of heart rhythm sampling and interpretation in an asymptomatic high risk population based in the community.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee - Wales Rec 6, 27/11/2014, ref: 14/WA/1227.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Patients at increased risk of developing atrial fibrillation

Interventions
Patients will be randomised 1:1 to either the AliveCor® (intervention) group or the standard care (control) group:
1. Patients in the AliveCor® group use the heart rhythm monitor, an electrocardiogram (ECG) device, and submit ECG readings to the study coordinators twice a week for 12 months
2. Patients in the standard care group may attend clinic after 12 months
Both groups have telephone contact at week 12 and 32. Patient data will be collected: a review of medical notes for any cardiac events including new diagnosis of atrial fibrillation, occurrence of stroke or transient ischaemic attack, commencement of anticoagulant and survival status at 12 months

Intervention Type
Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
AliveCor®

Primary outcome measure
Total number of new atrial fibrillation diagnoses within study period

Secondary outcome measures
1. Average time to diagnosis
2. Time to anti-coagulation
3. Patient compliance with monitoring
4. Patient satisfaction with monitoring

Overall study start date
01/04/2014

Completion date
12/12/2016

Eligibility

Key inclusion criteria
1. Male or female 65 years+ with one or more of the following risk factors, or 75 years+ with or without these risk factors;
1.1. Hypertension currently treated
1.2. Blood pressure >130/80mmHg not treated
1.3. Any previous stroke or transient ischaemic attack (TIA)
1.4. Diabetes (type 1 or type 2)
1.5. Heart failure
1.6. Ischaemic heart disease
1.7. Peripheral artery disease
2. Local access to the internet

Participant type(s)
Patient

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
1000

Total final enrolment

1001

Key exclusion criteria
1. Known atrial fibrillation
2. Currently receiving anticoagulants
3. Known contraindication to anticoagulation (chronic haematology conditions/previous haemorrhagic stroke/ongoing bleeding/liver disease)
4. No access locally to internet
5. Unable to operate the AliveCor® system

Date of first enrolment
09/02/2015

Date of final enrolment
01/08/2015

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Joint Clinical Research Facility - Swansea University
Singleton Park
Swansea
United Kingdom
SA2 8PP

Sponsor information

Organisation
ABMU Health Board

Sponsor details
1 Talbot Gateway
Baglan Energy Park
Port Talbot
SA12 7BR
Port Talbot
Wales
United Kingdom
SA12 7BR

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type
Government

Funder Name
Telehealth Grant - Welsh Assembly Government (UK)

Funder Name
AliveCor, Inc. (USA)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/11/2017		Yes	No
HRA research summary			28/06/2023	No	No
Results article		03/05/2023	17/08/2023	Yes	No