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

Submission date	Recruitment status	Prospe
07/04/2015	No longer recruiting	[] Protoc
Registration date 09/07/2015	<b>Overall study status</b> Completed	[_] Statist
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Last Edited 17/08/2023	<b>Condition category</b> Circulatory System	[_] Individ

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# 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 12month 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**

JCRF ILS2 Swansea University Singelton Park SA2 8PP Swansea United Kingdom SA2 8PP

# 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

 Known atrial fibrillation
Currently receiving anticoagulants
Known contraindication to anticoagulation (chronic haematology conditions/previous haemorrhagic stroke/ongoing bleeding/liver disease)
No access locally to internet
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

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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?
<u>Results article</u>	results	07/11/2017		Yes	No
HRA research summary			28/06/2023	No	No
<u>Results article</u>		03/05/2023	17/08/2023	Yes	No