ISRCTN12144707 https://doi.org/10.1186/ISRCTN12144707

Comparing the Rapid Rhythm System to 12-Lead ECG to identify older patients with atrial fibrillation in primary care

Submission date 22/06/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/07/2016	**Overall study status** Completed	
Last Edited 26/05/2021	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Stroke is responsible for around 11% of deaths in the UK. More than 900,000 people live with the after effects of stroke. Care for stroke sufferers is a significant social and economic burden for families, the NHS and wider economy. Atrial Fibrillation is a condition in which the electrical control centre of the heart (sinus node) does not send signals properly, leading to uncoordinated signals causing the heart to beat irregularly and often very fast. People suffering from AF have a much higher risk of developing other problems, such as stroke. Prevention of stroke in people with AF is usually achieved using blood thinning medications, such as warfarin, however this is not always effective and there is a risk of serious bleeding. The risk of stroke also increases as people age. Not all patients with AF have any symptoms and many more patients at risk could be identified if screening for Atrial Fibrillation in the over 65s were made quicker and easier. Currently the best form of diagnosing AF (the 'gold standard') is a 12-lead Electrocardiogram (ECG), which requires 10 electrodes (sticky pads that conduct electricity) to be placed on the chest, arms and legs, to measure electrical activity in the heart. The Rapid Rhythm System is a handset with 6 electrodes, held against a patient’s chest and a 4 electrode chest lead attachment. The Rapid Rhythm System requires less undressing and can be performed seated rather than lying down. This could help make screening for Atrial Fibrillation more practical in GP surgeries. The aim of this study is to find out whether the Rapid Rhythm System is as effective a tool for diagnosing AF as the gold standard.

Who can participate?
All patients over the age of 65 attending participating medical centres.

What does the study involve?
Participants attend one appointment at their local GP surgery. During the visit, they undergo a standard 12 lead ECG as well as testing with the Rapid Rhythm System. Patients diagnosed with Atrial Fibrillation or other heart abnormalities are confirmed by a Cardiologist (heart doctor) and proceed to routine care. The results of the two tests are then compared in order to work out how accurately the Rapid Rhythm System is able to identify AF compared to the gold standard.

What are the possible benefits and risks of participating?
Participants benefit from the opportunity of undergoing screening for AF, which is not normally widely available. Direct risks for patients are limited to the potential for anxiety over procedures, or results, that are common to all health screening activities. GPs will assess patient recruitment lists to identify patients for whom anxieties or burden may be a particular issue.

Where is the study run from?
Swan Lane Medical Centre, Bolton and nine other medical centres in England (UK)

When is the study starting and how long is it expected to run for?
June 2015 to December 2016

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

Who is the main contact?
Dr Jonathan Lamb

Contact information

Type(s)
Public

Contact name
Dr Jonathan Lamb

Contact details
Centre For Primary Care
Institute of Population Health
Willliamson Building
Oxford Road
Manchester
United Kingdom
M13 9PL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol Version 2 1 Date 26.02.16, NIHR i4i II-C1-0412-20002

Study information

Scientific Title

A diagnostic accuracy study comparing the use of the Rapid Rhythm System to 12-Lead ECG to identify atrial fibrillation in over 65s in primary care

Study objectives
The aim of this study is to test the performance of the Rapid Rhythm System against the 'gold standard' 12 lead ECG in identifying Atrial Fibrillation in GP surgeries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - South Birmingham Research Ethics Committee, 29/02/2016, ref: 16/WM/0022

Study design
Multi-centre cross-sectional diagnostic accuracy study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
The study involves screening patients for presence of atrial fibrillation using the Rapid Rhythm System and the current gold standard 12-lead ECG. The study is not randomised and no follow up is required. Patients will be invited to participate from GP practice list search using the FARSITE system, patients may also be opportunistically recruited by their routine primary care team. Both tests will be performed consecutively in either order at the same visit to a local practice. Both index and reference tests produce an ECG trace based on 12 electrodes. Both Rapid Rhythm system and conventional 12-lead ECG will be anonymised and interpreted blind by a panel of two cardiologists, in the event their diagnoses disagree results will be passed to a third cardiologist for interpretation blind to the prior interpretations. ECG results for clinical diagnostic purposes and for feedback to patients will be provided by approved supplier Technomed in a process fully independent of the study ECG interpretation. Any patients with problems identified will proceed to routine treatment.

Intervention Type

Device

Primary outcome measure
Diagnostic accuracy of the ECG trace from the Rapid Rhythm System at identifying atrial fibrillation (AF) compared to the ECG trace from the 12-lead is determined through assessing the sensitivity (ability to correctly identify patients with AF) and specificity (ability to correctly identify those without AF) of the RR compared to the Gold Standard 12-lead ECG, based on the diagnosis decisions made by the expert cardiology panel from the ECG traces from each system. Both ECG traces will be taken at the same time point and no follow up is involved.

Secondary outcome measures
Secondary accuracy measures:
Positive and negative predictive values (percentages confirmed by the 12-lead ECG to have/not have AF, out of all those classified as such using the RR).

An additional analysis will be conducted to compare the findings from the RR and 12-lead ECG to any pre-existing diagnoses of AF, taking from each patient's medical record.

A further analysis will make a comparison between two different configurations for the RR device. The device can be operated as either 8-lead from the handset alone or 12-lead using the handset with chest lead attachment. This is an adjunct technical analysis of device characteristics, not a performance measure. For this purpose the 8-lead data will be extracted from the full 12-lead and results for the two configurations compared using correlational and other analysis to determine the extent of agreement across the variables:
1. Rate
2. R-R interval
3. PR interval
4. QRS duration
5. QT interval
6. P-wave frontal axis
7. QRS-frontal axis
8. T-wave frontal axis
9. R/S amplitude in V1 and V2
10. R/S ratio in V1 and V2

Overall study start date
01/06/2015

Completion date
31/03/2017

Eligibility

Key inclusion criteria
All patients over the age of 65, including those with prior atrial fibrillation diagnoses.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Patients with implanted pacemakers, or defibrillators
2. Those unable to provide informed consent
3. Those considered by GPs to be inappropriate (e.g. due to terminal illness)

Date of first enrolment
07/10/2016

Date of final enrolment
30/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Swan Lane Medical Centre
Swan Lane
Bolton
United Kingdom
BL3 6TL

Study participating centre
Bodey Medical Centre
Ladybarn Court
28 Ladybarn Lane
Fallowfield
Manchester
United Kingdom
M14 6WP

Study participating centre
Bollington Medical Centre
Wellington Road
Bollington

United Kingdom
SK10 5JH

Study participating centre
Barlow Medical Centre
828 Wilmslow Road
Didsbury
Manchester
United Kingdom
M20 2RN

Study participating centre
Firsway Health Centre
121 Firsway
Sale
United Kingdom
M33 4BR

Study participating centre
Minden Family Practices
3rd Floor
Moorgate Primary Care Centre
22 Derby Way
Bury
United Kingdom
BL9 0NJ

Study participating centre
West Timperley Medical Centre
21 Dawson Road
West Timperley
Altrincham
United Kingdom
WA14 5PF

Study participating centre
Bridge House Medical Centre
11 Ladybridge Road
Cheadle Hulme

Cheadle
United Kingdom
SK8 5LL

Study participating centre
Northenden Group Practice
489 Palatine Road
Northenden
Manchester
United Kingdom
M22 4DH

Study participating centre
Woodlands Medical Centre
Chadderton Town Health Centre
Middleton Road
Chadderton
Oldham
United Kingdom
OL9 0LH

Sponsor information

Organisation
University of Manchester

Sponsor details
Research Governance
Ethics and Integrity Manager
Floor 2 Christie Building
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

ROR
https://ror.org/027m9bs27

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
1. Study results will be disseminated though the Atrial Fibrillation Association
2. Planned publication in a high impact specialised medical journal

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
Participant level data will be used in further development of the Rapid Rhythm ECG device and may be commercially sensitive. Participant level data will be held by Rapid Rhythm Ltd. Rapid Rhythm Ltd is a University of Manchester, Central Manchester University Hospitals NHS Foundation Trust (CMFT) spin out company established through NIHR i4i. CMFT and the grant holder Dr Fitzpatrick are minority shareholders in Rapid Rhythm Ltd.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No