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

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