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

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

#### 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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Oxford Road
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## Additional identifiers

#### Protocol serial number

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

#### Study type(s)

Diagnostic

#### 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(s)

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.

#### Key secondary outcome(s))

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. ORS-frontal axis
- 8. T-wave frontal axis
- 9. R/S amplitude in V1 and V2
- 10. R/S ratio in V1 and V2

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Senior

#### Sex

All

#### 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

**United Kingdom** 

England

## 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

#### 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**

#### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes