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The use of a hand-held electrocardiogram (ECG) monitor to diagnose paroxysmal atrial fibrillation at high risk of stroke

Submission date	**Recruitment status**	[X] Prospectively registered
24/10/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/11/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/08/2016	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Our study aims to find out whether or not a simple machine is as effective as other techniques at identifying an intermittent, irregular heart rhythm called paroxysmal atrial fibrillation (PAF). PAF is a risk factor for stroke. It is widely thought that long periods of this heart rhythm, in particular greater than 24 hours, confer a higher risk of stroke. PAF can be notoriously difficult to identify, because often patients have no symptoms and because of its intermittency.

Who can participate?

We plan to identify patients who already have PAF and may not be aware of it. These people should be over 18 years of age and should be able to use our electrocardiogram (ECG) machine (with no history of significant dementia for example). Patients who have a particular type of pacemaker (with two leads, one lead in the atrium of the heart) will pick up this heart rhythm. Additionally, this rhythm will also be identified in patients who have an implantable loop recorder (a device inserted under the skin, often placed because of unexplained palpitations or black-outs). If PAF is documented during a routine pacemaker check at your local hospital (the Royal Surrey, St Peters or Frimley Park), and it lasted for at least 24 hours in the previous month, you will be asked if you might consider participating in the trial. Of particular importance, if this is a new finding, your GP or hospital doctor will be informed of this in order to treat you, if necessary with aspirin or warfarin, to thin the blood to prevent the potential consequence of stroke.

What does the study involve?

If you agree to discuss possible participation with us, your details will be passed onto the research team and you will be given a patient information leaflet. You will subsequently be contacted by a nurse or doctor to arrange a meeting at the Royal Surrey County Hospital, Guildford, the principal hospital conducting this study. At this meeting, you will be shown a short video and the research team member will talk to you further. It will be explained how we are testing two different devices on each individual to see how effective they are at detecting PAF. The first of these is a portable, hand-held ECG monitor. This will require recordings of your heart rhythm lasting 30 seconds, twice daily for 3 months. The second machine will be worn

continuously around the neck for 7 days during this time period. Following this 3-month interval you will be required to have one further pacemaker check at your local hospital. At the end of this consultation, you will be able to ask any questions you may have. If you agree to participate, you will be asked to sign a consent form. At the same time, you will be asked a few short questions about your medical history and medications. You will be shown in full how to use the two devices mentioned above. Lastly you will have a 5 ml blood sample taken.
30 subjects will be recruited from three pacemaker clinics throughout Surrey, UK. These patients will already have a permanent pacemaker or implantable loop recorder in place. They will have documented atrial fibrillation (an irregular heart rhythm predisposing to stroke) in the last month for a duration greater than 24 hours. Patients who have given their consent will undertake twice daily ECG recordings (30 seconds each) for 3 months with a hand-held ECG device. They will also wear a 7-day, continuous ECG monitor (R-test). Following this study period they will have a final pacemaker check. Accuracy of detection of PAF will be compared between the various methods.

What are the possible benefits and risks of participating?
PAF is a risk factor for stroke. It can be difficult to diagnose and treat appropriately. We are always looking for better ways to do this, and we think that a portable ECG machine is an effective and simple method, but we need to prove this. The two devices that we wish to compare are discrete, compact and will not cause any discomfort to participants. We appreciate that participation in this study may cause some degree of inconvenience; however, we would be immensely grateful for your participation in this trial. We believe that with your help we may be able to show that a handheld ECG machine has the ability to diagnose PAF readily. As a consequence of your participation, we may be able to identify such individuals in the future and treat them appropriately in order to reduce the number of, all too frequent, disabling strokes.

Where is the study run from?
The Royal Surrey County Hospital, Guildford.

When is the study starting and how long is it expected to run for?
We plan to start this trial in December 2012 and envisage that it will be completed in June 2013

Who is funding the study?
The study is funded by HASTE (Heart and Stroke Trust Endeavour - http://haste.cardiovasculararclinics.co.uk).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Study information

Scientific Title
Validation of a single channel, patient-activated, hand-held electrocardiogram (ECG) device in the diagnosis of paroxysmal atrial fibrillation with high embolic risk

Study objectives
Current study hypothesis as of 05/10/2012:
Paroxysmal atrial fibrillation (PAF) predisposes to stroke. It is thought that the longer the duration of PAF the higher the stroke risk. Identification of these individuals, and appropriate management with anticoagulation, should reduce the rate of stroke.
A handheld ECG device will diagnose paroxysmal atrial fibrillation, with a high risk of stroke, with a high level of sensitivity and specificity.
A novel serum biomarker may detect paroxysmal atrial fibrillation identified in these subjects.

Previous study hypothesis until 05/10/2012:
Paroxysmal atrial fibrillation (PAF) predisposes to stroke. It is thought that the longer the duration of PAF the higher the stroke risk. Identification of these individuals, and appropriate management with anticoagulation, should reduce the rate of stroke.

The OMRON® handheld ECG device will diagnose paroxysmal atrial fibrillation, with a high risk of stroke, with a high level of sensitivity and specificity.

Please note that as of 05/10/2012 the following updates were made to the record:
1. The anticipated start date was changed from 01/04/2012 to 01/12/2012
2. The anticipated end date was changed from 01/10/2012 to 01/06/2013
3. The scientific title was changed from 'Validation of a single channel, patient-activated, hand-held electrocardiogram (ECG) device (OMRON®) in the diagnosis of paroxysmal atrial fibrillation with high embolic risk '

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective observational study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Paroxysmal atrial fibrillation (PAF)

Interventions
Current interventions as of 05/10/2012:
Subjects will be issued with two new methods of ECG monitoring (to be compared with the continuous, implantable ECG monitor already in place). The first method will involve twice daily recordings using the hand-held ECG device. This recording will take 30 seconds and will be taken for 3 months in total. The second method will involve a 7-day continuous ECG monitor. This will involve wearing a small, discrete ECG monitor around the neck for 1 week only.
Both these methods are not invasive and hence participants should not experience any adverse effects or discomfort from their usage.
A 5 ml blood sample will be taken peripherally to try to identify a novel microRNA biomarker to detect PAF. Samples will be taken on two occasions during attendance for the above monitoring exercise.

Previous interventions until 05/10/2012:
Subjects will be issued with two new methods of ECG monitoring (to be compared with the continuous, implantable ECG monitor already in place). The first method will involve twice daily recordings using the hand-held ECG device (OMRON®). This recording will take 30 seconds and will taken for 3 months in total. The second new method will involve a 7-day continuous ECG monitor (the R-test). This will involve wearing a small, discrete ECG monitor around the neck for 1 week only.

Both these methods are not invasive and hence they should not experience any adverse effects or discomfort.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The accuracy of a hand-held ECG device in the diagnosis of paroxysmal atrial fibrillation as compared to a 'gold-standard' implantable continuous monitoring device

Key secondary outcome(s))
Current secondary outcome measures as of 05/10/2012:
1. The accuracy of a hand-held ECG device compared to a 7-day continuous ECG monitoring device
2. The concordance of diagnosis of atrial fibrillation using all devices between a trained 'arrhythmia nurse' and trained cardiologists
3. The sensitivity and specificity of a novel microRNA biomarker in patients with confirmed PAF.

Previous secondary outcome measures until 05/10/2012:
1. The accuracy of a hand-held ECG device compared to a 7-day continuous ECG monitoring device
2. The concordance of diagnosis of atrial fibrillation using all devices between a trained 'arrhythmia nurse' and trained cardiologists

Completion date
01/06/2013

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/10/2012:
1. Age > 18 years
2. Duration of PAF > 24 hours in the last month
3. Capacity to consent to study
4. No new initiation of anti-arrhythmic agents.
5. Pacing less than 25% of time at last pacing check

Previous inclusion criteria until 05/10/2012:
1. Age > 65 years
2. Duration of atrial fibrillation > 24 hours in the preceding one month

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 05/10/2012:
1.Inability to use hand-held ECG/R-test due to physical or cognitive impairment

Previous exclusion criteria until 05/10/2012:
1. Cognitive impairment (hence inability to use the handheld ECG device)

Date of first enrolment
01/12/2012

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Cardiology
Guilford
United Kingdom
GU2 7XX

Sponsor information

Organisation
Royal Surrey County Hospital (UK)

ROR
https://ror.org/02w7x5c08

Funder(s)

Funder type
Research organisation

Funder Name
HASTE (Heart and Stroke Trust Endeavour - http://haste.cardiovasculararclinics.co.uk).

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration