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Post-stroke rapid assessment of atrial fibrillation

Submission date	Recruitment status	[ ] Prospectively registered
11/04/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/05/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/05/2023	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Practice in the detection of paroxysmal atrial fibrillation differs across the UK. On arrival at a stroke unit, a 12-lead ECG will be performed as well as a physical examination. This will very rarely detect PAF however due to the condition's transient nature and lack of symptoms in an estimated 90% of cases. Longer-term bedside monitoring is recommended but can often be interrupted or stopped prematurely. It also requires manual interpretation which is hard to achieve when clinicians do not have the time to observe monitors over extended periods. It has been widely shown that to a point, the longer monitoring is performed, the higher the chance of PAF detection in the post-stroke population. A regional audit conducted by our team found that the average waiting time for cardiac investigations in the North East is 5 weeks after discharge with a further 9 working days between the wearing of the tape and the generation of the report. In this study, the team are able to monitor patients from the first day of their admission and in a lot of cases rule PAF in or out before they are discharged. The aim of this study is to explore whether monitoring rapidly post-stroke is likely to detect more PAF than current standard practice does.

Who can participate?
Participants will all be inpatients in the hyperacute stroke unit at the Royal Victoria Infirmary who have had a suspected stroke within the last 48 hours.

What does the study involve?
After consent has been given for the trial, the study team will randomise the patient into either an active or standard treatment arm. Being assigned to the active arm would mean 7 days of prolonged cardiac monitoring commencing that day. Participants are able to discharge whilst still wearing the device and return to the stroke clinic in 1 week for removal and analysis. If assigned to the standard arm, a referral will be made to cardiology and the participant will receive an appointment for a 24-hour Holter monitor an average of 5 weeks later. After wearing either device the study team will ask participants to complete a short questionnaire detailing their experience.

What are the possible benefits and risks of participating?
The study team do not anticipate this device causing any major issues relating to this study.

Participants may benefit from an earlier monitoring period if randomised to the active arm of this study.
Superficial damage and/or irritation to skin is possible when wearing electrodes as the trial device will likely be worn longer than standard telemetry. The study team will regularly assess this and remove it prematurely if the PI feels this is necessary.
The standard 24-hour monitor can detect additional heart rhythm abnormalities whereas the 7-day monitor will exclusively screen for PAF. In 98% of stroke patients, these additional findings would not have any clinical relevance. However, in 1-2% of patients, these findings may need attention from a heart specialist.

Where is the study run from?
Newcastle Hospitals NHS Foundation Trust- Stroke research team, Royal Victoria Infirmary (UK)

When is the study starting and how long is it expected to run for?
April 2019 to June 2023

Who is funding the study?
1. Bridging Stroke, a branch of Newcastle Hospitals Charity (UK)
2. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Beth Holland, beth.holland1@nhs.net

Contact information

Type(s)
Principal investigator

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
286020

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 47581, IRAS 286020

Study information

Scientific Title
Post-stroke rapid assessment of cardiac arrhythmia evaluation - The Pace Study

Acronym
PACE

Study objectives
How does rapid prolonged in-house cardiac monitoring compare to the current standard care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/02/2021, North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHS BT Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ, UK; +44 (0)207 104 8079; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 20/NE/0264

Study design
Randomized interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke, cerebrovascular diseases

Interventions

The trial will follow a 1:1 randomisation of 150 patients.
The study team have chosen a randomised controlled trial to best compare two groups and avoid any intentional or unintentional bias as best they can.
Most of this trial will take place in the few days after the participant has been admitted for a stroke. While the participant is an inpatient in the stroke ward, the study team will explain the trial, issue an information sheet, and ask them to sign a consent form if clinicians think they would be suitable candidates.
The study team are unable to run a blinded trial in this instance as the devices and pathway are significantly different to one another, however, the intervention is not susceptible to the placebo effect.
The study team will endeavour to offer every control arm patient the new monitoring pathway after their participation in the trial has ended (if PAF is still suspected as an underlying cause for their stroke) 50% of participants will be randomised into the control arm. Patients in this arm will still receive all the standard care that they would normally. A placebo arm would not be advisable or necessary as the study team are comparing two methods of the same investigation rather than two contrasting investigations. Monitoring in both arms is performed via the same medium- electrical activity of the heart.
If allocated to the active arm, a cardiac monitor will be fitted as soon as appropriate by the research team. In most cases, this will be within 48 hours of admission.
The data this monitor collects will be analysed every 24 hours for a maximum of 7 days. If after 24 hours it reports that no Paroxysmal Atrial fibrillation is detected or an increased risk of PAF is detected, the monitor will be returned to the patient for another period of 24 hours at least. This daily analysis is a simple procedure as the device can be detached from the electrodes and the rest of the electrodes and wiring will remain fitted to the patient. If after 24 hours PAF has been detected, the device will be removed, and the appropriate course of action will then be taken. This ends the participation in the trial.
This trial does not dictate what the clinician must do if PAF is detected- this will fall to the judgement of the clinician and be governed by national guidance on anticoagulation for suspected stroke or TIA. It is likely that the participants in the trial will be discharged to their homes before 7 days of monitoring is complete, particularly in milder cases. In this instance, if no PAF has already been detected, the study team will ensure the device is securely attached and plan for them to return once a full 7 days or 168 hrs is complete. As the battery only lasts for 7 days it does not matter if the return visit is slightly delayed. No data will be collected post 7 days meaning no patient will have an unfair advantage in this sense. At the return visit (if this is needed) the study team will analyse the home data and go through questions on the tolerability of the device and if any problems were encountered. Transport costs will be covered by the trial. The trial portion of this visit should take no longer than 30 minutes.
This will end the patient’s participation in the trial and any clinical decision based on the report will be left to the discretion of the P.I and colleagues from a standard care viewpoint. It is likely that a discussion regarding anticoagulation options will take place and the study team foresee medication being prescribed at this visit. At 6 weeks post-discharge, the study team will collect data from every standard arm participant’s cardiac appointment and conduct a brief telephone follow-up call. Data points will include the date of the tape, the results of monitoring and how long they waited for the appointment. It is possible that some patients will not have had the tape fitted by this point. If this is the case, they will be recorded by default as 'no PAF detected' and it will be noted that no investigation was made available during this window. From a clinical standpoint, a wait of over 6 weeks is unacceptable and the proportion of trial patients who must wait longer than this will be an important data point.

Due to this being a small pilot study, the study team do not currently plan on conducting interim analyses. The study team will however review safety data regularly and make the appropriate intervention if necessary.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bittium Faros 360 3-Channel ECG for Cardiac Monitoring

Primary outcome(s)
The following primary outcome measures are assessed using patient medical records at 6 weeks post-discharge:
1. The number of cases of paroxysmal atrial fibrillation (PAF) detected using a revised pathway for cardiac monitoring of rapid fitting and longer-term monitoring as compared with the standard methods
2. The number of patients who commenced long-term anticoagulation as a result of detected PAF based on 24-hour recording versus the active arm

Key secondary outcome(s))
1. Number of patients with PAF lasting more than 30 seconds will be compared in both arms measured using patient medical records at 6 weeks post-discharge
2. The time taken (in hours) from stroke onset to PAF detection in those with positive reports in both arms measured using patient medical records at 6 weeks post-discharge
3. Number of visits, workforce burden and associated costs with each pathway will be compared as a whole measured using patient medical records at one timepoint. The number of visits will be counted and recorded. The length of each visit (minutes) will also be recorded. Additional investigations and the number of these performed at each visit will be recorded. These three factors are added to determine workforce burden and costs according to the NHS national tariff.
4. Projected number of strokes prevented based upon the additional number of patients receiving long-term anticoagulation following PAF detection in both arms measured using patient medical records at one timepoint. To work with health economics to determine this using the latest research on AF prevalence combined with national tariff info. The number of patients receiving long-term anticoagulation will be recorded in each group. Comorbidities, age, and stroke risk factor score CHA_2DS_2-VASc Score) are all taken into account.

Completion date
01/06/2023

Eligibility

Key inclusion criteria
1. Suspected acute ischaemic stroke
2. Suitable for monitoring and anticoagulation
3. Capacity to consent or availability of legal representative

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Known AF or admission ECG detects new AF or PAF.
2. Imaging of the brain (CT or MRI) confirming non-ischaemic stroke
3. Currently anticoagulated or has alternative indications for long-term anticoagulation
4. Contraindication to use of long-term anticoagulants
5. Patient unable to return the cardiac monitor to the RVI
6. Use of previous Implantable Loop Recorder for detection of PAF within the last 6 months
7. Dermatological condition or allergy prohibiting use of electrodes/skin adhesives
8. Known pacemaker or other devices that may contraindicate the use of monitoring device
9. Patient and/or relative unable to communicate sufficiently in English where no appropriate translator is available.

Secondary check at 14 hours:
1. Patient now for palliation
2. Alternative non-cardioembolic cause for stroke confirmed
3. On review patient was identified as non-stroke

Date of first enrolment
08/04/2021

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
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Newcastle upon Tyne
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NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Funder Name
Bridging Stroke, a branch of Newcastle Hospitals Charity

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mrs Michelle Fawcett, Michelle.fawcett6@nhs.net. De-identified quantitative patient data points that are relevant for external users will be shared beginning 3 months and ending 36 months post-publication. Consent is not explicitly asked for data sharing outside the

trust in the consent form. The PIS makes it clear that the study team will share results in the publication however this will all be de-identified. No qualitative information e.g. free text answers to interview questions will be shared with other researchers. De-identification is performed on randomisation. Only members of the Newcastle Hospitals Stroke team have access to the personal information of participants. Participants are given a unique study ID that they cannot be identified from outside of the trial. The team cannot extrapolate the results to the use of other similar cardiac devices. Only the Bittium Faros with adjunct Apoplex software was tested.

IPD sharing plan summary

Available on request

Study outputs

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