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Early prolonged ambulatory heart monitoring in patients with stroke

Submission date	Recruitment status	[X] Prospectively registered
28/01/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/01/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/07/2019	Circulatory System	

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is a common heart condition, affecting millions of people worldwide. The heart consists of two upper chambers (atria) and two lower chambers (ventricles). Inside the right atrium, a cluster of cells (sinus node) are responsible for firing electrical signals into the heart muscle causing the heart to beat regularly (sinus rhythm). When a person is suffering from AF, the normal signals from the sinus node do not work properly, causing other parts of the atria to fire chaotically. These uncoordinated signals cause the heart to beat irregularly and often very fast (arrhythmia). People suffering from AF have a much higher risk of developing other problems, such as stroke or heart failure. It is common practice to monitor a patient's heart continuously for 24 hours after they have had a stroke or TIA (transient ischaemic attack also referred to as a "mini-stroke") in order to find out if a person is suffering from AF. Paroxysmal atrial fibrillation (PAF) is where the episodes of AF come and go, usually stopping within 48 hours on their own. This means that a standard heart monitoring test may not be able to detect it as it cannot be guaranteed when an episode will happen. Recent studies have shown that monitoring the heart for a longer period of time could be a better way of detecting PAF in patients after they have had an unexplained stroke or TIA (cryptogenic stroke or TIA). The aim of this study is to find out whether early prolonged heart monitoring (of up to 14 days) using a convenient wireless skin patch would be more effective than standard clinical practice (24 hour heart monitoring).

Who can participate?
Adults who have had a stroke or TIA in the last 72 hours who are not known to suffer from AF or blocked arteries in the neck (carotid stenosis).

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive standard Holter monitoring for 24 hours as an outpatient (standard practice). This involves having small sticky pads (electrodes) attached to the chest, connected to a machine to monitor the activity of the heart continuously. Participants in the second group also have standard Holter monitoring, however they also receive the new patch-based monitoring system (ZP). This involves a patch being applied to the chest which is kept in place for 14 days. On day 14, patients are asked to return the patch device by post so that the data can be assessed. Participants in

both arms attend a follow-up appointment at 90 days, in order to find out how many have developed AF, and how many have had another stroke or TIA.

What are the possible benefits and risks of participating?
Participants may benefit from improved chances of picking up an irregular heartbeat (AF) and so can be treated, which could lower their chances of further strokes or TIA's. Risks of participating are minor, however some participants may experience skin irritation and redness from the sticky patch attached to the skin.

Where is the study run from?
1. Princess Royal University Hospital (UK)
2. King's College Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2016 to January 2017

Who is funding the study?
Bristol-Myers Squibb (UK)

Who is the main contact?
Dr James Teo

Contact information

Type(s)
Scientific

Contact name
Dr James Teo

Contact details
Princess Royal University Hospital
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Orpington
United Kingdom
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Additional identifiers

Protocol serial number
20133

Study information

Scientific Title
Early Prolonged Ambulatory Cardiac monitoring in Stroke: A prospective randomised open blinded endpoint study

Acronym

EPACS

Study objectives
Early prolonged ambulatory cardiac monitoring detects more paroxysmal atrial fibrillation in stroke patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Surrey Borders Research Ethics Committee, ref: 15/LO/1534

Study design
Prospective randomised open blinded endpoint study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Ischaemic stroke

Interventions
Volunteers are randomised to standard cardiac work-up (24-hour Holter monitoring, CMP-arm) or a novel patch-based monitoring system (ZP-arm).

CMP-arm: Patients will receive current medical practice of ambulatory outpatient 24-hour Holter-monitoring only.

ZP-arm: In the baseline session, patients will have a patch applied to their anterior chest wall with the device kept in-situ for 14-days continuously (removed only for short-intervals, e.g. MRI-scans). On day 14, volunteers will receive a phone call reminder to return the device by post. Patients will also have the standard practice of a 24-hour Holter monitor.

All patients in both arms will also receive standard brain and vascular imaging, a routine 12-lead ECG and a transthoracic ECHO. Patients in both study arms will then be followed up for 90 days.

Intervention Type
Mixed

Primary outcome(s)
Total AF detection rate is determined using either a standard Holter electrocardiogram or a Ziopatch cardiac monitor at day 28.

Key secondary outcome(s))
1. AF-detection-rate is determined using Holter-monitor versus ZioPatch cardiac monitor within the same patients (intragroup) using at day 90
2. AF detection rate is determined using Holter-monitor versus ZioPatch cardiac monitor at day 28

3. Anticoagulation rate is determined using review of patient clinical record at day 90
4. Ischaemic stroke or TIA rates is determined using review of patient clinical record at day 90
5. Mortality at is determined using review of patient clinical record at day 90
6. Time-to-reporting of cardiac monitoring is determined using review of patient clinical record at day 90
7. Patient feedback on cardiac monitoring is determined using questionnaires at day 90

Completion date
14/02/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Cryptogenic ischaemic stroke in first 72 hours in patients not known to have atrial fibrillation (AF) or >50% carotid stenosis ipsilateral to an anterior circulation stroke
OR
3.. Cryptogenic TIA's in first 72 hours in patients not known to have AF or >50% carotid stenosis, where the ABCD2 >4 and
3.1. ABCD2 score >4
3.2. Hemianopia
3.3. Hysphasia
3.4. DWI-positive MRI in a non-lacunar distribution

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
116

Key exclusion criteria
1. Patients unable to provide informed consent
2. Patients who are not candidates for anticoagulation
3. Patients already on anticoagulation for other causes
4. Patients with significant carotid stenosis (>50% carotid stenosis)
5. Patients with known atrial fibrillation
6. Patients with a non-AF cardiac condition requiring anticoagulation
7. A currently implanted cardiac device (e.g. Pacemarker, Implanted Cardiac Defibrillator)

Date of first enrolment
03/02/2016

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital
Kings College Hospital NHS Foundation Trust
Denmark Hill
London
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SE5 9RS

Study participating centre
Princess Royal University Hospital
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Farnborough Common
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Sponsor information

Organisation
Kings College Hospital NHS Foundation Trust

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Industry

Funder Name
Bristol-Myers Squibb

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/07/2019	30/07/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes