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PATIENT NOTIFICATION

This patient notification contains information about our research study - **Use and impact of the pre-hospital 12-lead electrocardiogram in the primary PCI era. Mixed method study (PHECG-2)** - and how it will utilise a heart attack patient's data.

About the study

When someone has a suspected heart attack the ambulance service are equipped to perform a heart tracing to determine whether they need to take the patient to a specialist hospital department. Our previous research showed that patients who had this test – pre hospital electrocardiogram, or PHECG – had a better chance of survival. But a third of patients who should have didn't receive the test. Our previous research took place at the time when the main treatment for heart attack was 'clot busting' drugs. Treatment has since changed and is now mainly with balloons and stents. We don't know if the PHECG is still associated with benefit in the modern era and want to look at data from a large national heart attack audit (Myocardial Ischaemia National Audit project or MINAP) to assess this. We also want to understand more about how ambulance staff decide to perform the PHECG test, so plan to look at ambulance records and hold focus group discussions with ambulance staff. Using these different types of research methods we hope to be able to learn about barriers and facilitators to the use of the PHECG test so more patients benefit and have better outcomes following their heart attack.

Most patients who have had a heart attack will have a record about their episode of ill health in MINAP. Because MINAP mainly collects data on what happens to the patient in hospital, we will also be linking each record to Office for National Statistics mortality data to see whether a patient is alive at 30 days and one year after their admission to hospital. This will to allow us to compare patient outcomes (survival) for those who had and did not have PHECG. Similarly, we will collect additional data for a sample of patients from the three participating ambulance services in England and Wales; this sample will be identified from the MINAP database. We will look at patients who did and did not receive PHECG which will enable us to see how these two groups of patients differ or what they have in common.

More information about our study can be found on the clinicaltrials.gov website by clicking here or searching by the registration number NCT03699137.

Our research is funded by the British Heart Foundation.

What data will be collected and how it will be used?

Although MINAP collects personal data for data quality and data linkage purposes, such data will not be available to the research team. The research team will only receive pseudo-identifiers – a long sequence of letters and numbers - that enables us to link the datasets in question (MINAP with date of death/vital status and ambulance records). It will not be possible for the research team to identify any patient from this code.

Data will be stored in a secure environment within the Swansea University Trials Unit and only study statisticians will have access to this data. The security arrangements within both Swansea University and Kingston University (the lead organisation for the study) have been approved by NHS Digital and the National Institute for Cardiovascular Outcomes Research (NICOR).

Our research has been approved by the London – Hampstead NHS Research Ethics Committee (ref: 18/LO/1679) and recommendation for approval has also been given to the Health Research Authority by the Confidentiality Advisory Group (ref: 18/CAG/0164).

How we will report our findings

At the end of the study we will publish our results in peer-reviewed, Open Access academic journals, ensuring that anyone who wishes to can access the results free of charge. We will also present the study at relevant cardiology and emergency conferences.

In addition, we will produce an end of study report for interested parties including:

- Our funder – the British Heart Foundation
- The Health Research Authority, including the Research Ethics Committee and Confidentiality Advisory Group who had given support to approve our research
- Ambulance staff who participated in the focus groups

It will not be possible to identify any patient from the published results.

Can I opt out?

Yes, you can do so using the *national data opt-out service* that allows people to opt out of their confidential patient information being used for research and planning. More information on this is available on the NHS Digital website: https://digital.nhs.uk/services/national-data-opt-out-programme

In relation to MINAP, if you do not wish your data to be used in this study, please contact James Chal, NICOR Chief Operating Officer in writing to the following address: NICOR, Barts Health NHS Trust, Second Floor, 1 St Martin's Le Grand, London EC1A 4NP or by email at: j.chal@nhs.net or by telephone on: 0203 765 8542.

Your care and treatment will be not be affected by choosing to opt out of your data being used in the study.

What if there is a problem?

If you have a concern or a complaint about any aspect of this study, please contact in the first instance the study Chief Investigator, Professor Tom Quinn at t.quinn@sgul.kingston.ac.uk.

If you are not satisfied with the response you receive, please contact:

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