Patient Information Sheet

FISH and CHIPS

FFRCT in Stable Heart disease & CCTA Helps Improve Patient care and Spending

Why is this study important?

Chest pain may be a symptom that is related to a narrowing of the heart blood vessels (coronary artery disease [CAD]). This chest pain, known as angina, can result in a reduced quality of life and, if not diagnosed and managed appropriately, could result in a heart attack. Guidelines recommend the use of tests to help diagnose and manage chest pain 'angina' patients. Coronary computed tomography angiography (CCTA) is a test that takes images of the heart blood vessels. It is the main test for patients presenting with angina, as it is excellent at saying when the heart blood vessels are normal, and can be reassuring for patients. However, when narrowing's are present CCTA lacks the ability to tell whether they are causing the patient's symptoms.

A new technology, CT-derived fractional flow reserve (FFRCT) uses the CCTA images to make a 3D model of the heart blood vessels that shows whether there is a limitation in the blood flow to the heart which is causing the symptoms. The National Institute for Health and Care Excellence (NICE) recommends the use of *Heartflow©* FFRCT in a chest pain pathway. However, use of this new technology remains limited due to funding restrictions and uncertainty as to its benefit in the NHS.

What is the aim of this study?

This study aims to determine the extent to which the new FFRCT technology is safe and reliable, provides a quicker time to diagnosis for the patient, reduces the need for further tests and thus does the investment in the test represent good value to the NHS.

Why is my data being used?

You have been identified as having had a CCTA for the investigation of possible angina at your local hospital. The research study would like to use the information that is collected as part of your routine health care to find out what happened after you had your CT scan. This will include finding out if you required any further tests, how many hospital visits you needed and whether you went on to have any treatments for coronary artery disease, such as coronary stenting or bypass surgery. It may be that as part of your routine clinical care that your CT scan underwent an FFRCT performed by *Heartflow©*. We will be assessing whether those individuals that received a *Heartflow©* FFRCT had different outcomes to

those individuals who did not have the FFRCT. The study will also look to find out whether any individuals went on to have a heart attack, despite having had the CT scan.

How will my information be used for research and is it confidential?

All NHS organisations are expected to participate and support health and care research. The data that the study is using is part of the routine data that is collected by your hospital and reported to NHS England. The study will be asking your hospital to identify you as person who has had a CT scan and we will use your unique patient identifier (NHS Number) to collect the data from NHS Digital. Doing this makes maximum use of the information you have provided and allows researchers to discover more. Some of the information may be used in future research looking at social and economic factors affecting health.

All data will be depersonalised so that you cannot be identified, and all data will be stored securely in accordance with the provisions of the Data Protection Act 2018.

What is the benefit of my data being collected for the study?

This research explores the use of a new technology for the diagnosis and treatment of heart disease. Patient and public groups reported to us that they felt it was important to assess the potential benefit of *Heartflow's* FFRCT in diagnosing and managing coronary artery disease. In particular, the ability to reduce the need for invasive tests (coronary angiogram) and reduce the time to a diagnosis of angina.

The Health Research Authority research ethics committees reviewed the research study to make sure that the research uses of data about you are in the public interest, and meet ethical standards.

What will happen once the study has finished?

Once the study has ended, the results will be written up and submitted for publication in a medical journal. You will not be identifiable in any published results. We do not routinely contact participants to inform them of the outcome of the research but a summary of the findings will be available on the University of Liverpool website.

Your choices about health and care research

All patients have the right to request that their data is not used for research purposes. Should you wish for your data **NOT** to be used as part of this study, please contact the

research team trial co-ordinator or your local hospitals research team (see below contacts) and they will remove you from the study.

Key Contacts:

Chief Investigator	Dr Timothy Fairbairn t: 0151 600 1477 e: timothy.fairbairn@lhch.nhs.uk
Trial Co-ordinator	Mr Ian Kemp t: 0151 228 1158 e: ian.kemp@lhch.nhs.uk
Sponsor	The University of Liverpool, University of Liverpool, Room G18, William Henry Duncan Building, 6 West Derby Street, Liverpool, L7 8TX t: 0151 600 1467 e: Vicky.wilkinson@lhch.nhs.uk
Funder(s)	Medical Research Council and Heartflow
Clinical Trials Unit	Liverpool Heart and Chest Clinical Trials \monitoring officer t: 0151 600 1013 e: Colette.mcgee@lhch.nhs.uk
Local- Principal Investigator	 t: e:
Local Research team	 t: e: