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Does CT-derived fractional flow reserve help reduce healthcare costs and improve patient care in a real-world setting?

Submission date
22/06/2022

Recruitment status
No longer recruiting

Registration date
29/07/2022

Overall study status
Completed

Last Edited
09/08/2023

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Coronary artery disease (CAD) remains the major cause of heart-related deaths and overall deaths in the United Kingdom. Angina is a symptom of chest pains that is a warning of the presence of CAD. In order to investigate patients with possible angina, doctors can perform a CT coronary angiogram (CTCA) that looks to identify CAD. Whilst CTCA is excellent at detecting CAD it cannot determine whether this is causing the patient's symptoms. A new technology, CT-derived fractional flow reserve (FFRCT), was introduced by NHS England in 2018 to help identify the patients with significant CAD that is causing angina. This study aims to look at the patients who had FFRCT and compare them to patients who didn't have this test to determine whether the new technology has been useful. The researchers will assess its impact on the length of the patient journey, the number of tests the patients required and whether there was any difference in heart attack and death rates.

Who can participate?
Patients aged 18 years and over who underwent a CTCA as part of an investigation for CAD between 2017 and 2020 at participating sites

What does the study involve?
A retrospective analysis of data captured from NHS digital's datasets.

What are the possible benefits and risks of participating?
There are no specific benefits to the participants involved as their care will have already occurred and this is a retrospective observational study. The benefits are establishing the potential benefit of this technology in the NHS.

Where is the study run from?
Liverpool Heart and Chest Hospital (UK)

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

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Tim Fairbairn, Timothy.Fairbairn@lhch.nhs.uk

Contact information

Type(s)
Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
285996

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 285996, CPMS 46652

Study information

Scientific Title
CT-derived fractional flow reserve in stable heart disease and coronary computed tomography angiography helps improve patient care and societal costs

Acronym
FISH and CHIPS

Study objectives
To determine whether a coronary computed tomography angiography (CCTA) and CT-derived fractional flow reserve (FFRCT) diagnostic pathway reduces health-related events, time to

diagnosis and overall healthcare costs compared to a ‘standard of care’ CCTA diagnostic chest pain pathway.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/02/2021, North West - Liverpool Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048118, +44 (0) 2071048035, +44 (0)2071048016; liverpoolcentral.rec@hra.nhs.uk), ref: 20/NW/0430

Study design
Pragmatic ‘real world’ multi-centre retrospective observational analytic cohort study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Participants will include all individuals who had a CCTA performed at an institute participating in NHS England’s Innovation and Technology Payment (ITP) programme during 2018-2020. All CCTA 12 months prior to and up to 24 months following the start of an FFRCT programme (total study period 36 months) will be assessed. The cohort from this population that received an FFRCT will be separately identified.

Patients will be followed up at 90 days, 12 months and a minimum of 24 months post CCTA for the pre-defined primary and secondary endpoints.

Intervention Type
Other

Primary outcome measure
Collected from NHS digital’s datasets for 90 days, 12 months and a minimum of 24 months follow-up post CCTA:
1. MI event rate, hospitalization for acute coronary syndrome, MI deaths and all-cause death
2. Downstream testing: numbers of non-invasive functional tests, and invasive coronary angiograms without revascularisation performed following the index FFRCT

3. Cost analysis: total cost to the NHS of the index test and all downstream investigations and hospital admissions

Secondary outcome measures
Collected from NHS digital's datasets for 90 days, 12 months and a minimum of 24 months follow-up post CCTA:
1. Time to diagnosis - trust referral to treatment (RTT) time
2. Qualitative assessment of the impact of the FFRCT health technology

Overall study start date
01/01/2019

Completion date
01/08/2023

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. CCTA for the assessment of coronary artery disease (CAD)

Participant type(s)
Patient, Population

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100000

Key exclusion criteria
1. Age <18 years
2. Coronary artery calcium scoring alone
3. CCTA in addition to a second CT investigation for a non-coronary indication (CT transcatheter aortic valve implantation [TAVI], CT aorta)
4. Previous CCTA within 6 months
5. Prior coronary artery bypass graft (CABG)/myocardial infarction (MI)
6. Entry into a separate FFRCT research study during the study timeframe

Date of first enrolment
01/03/2022

Date of final enrolment
22/06/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool Heart and Chest Hospital
Thomas Drive
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Sponsor information

Organisation
Liverpool Heart and Chest Hospital

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Sponsor type
Hospital/treatment centre

Website
http://www.lhch.nhs.uk/About-Us/

ROR
https://ror.org/000849h34

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be submitted for peer review with presentation and publication in high-impact peer-reviewed journals

Intention to publish date
26/08/2023

Individual participant data (IPD) sharing plan
Participant-level data will not be shared as per the Data Access Request Service (DARS) agreement

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	01/12/2020	30/06/2022	No	Yes
Protocol file	version 2	01/06/2022	30/06/2022	No	No
HRA research summary			28/06/2023	No	No