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Evaluating Fractional Flow Reserve computed from Cardiac CT images

Submission date
08/09/2017

Recruitment status
No longer recruiting

Registration date
13/12/2017

Overall study status
Completed

Last Edited
13/12/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims

Chest pain is one of the most common reasons for patients to attend cardiology (heart) and chest pain clinics. One of the causes of chest pain is a condition known as angina (pain resulting from the heart muscle not receiving enough blood). This is known as coronary artery disease (CAD) and is caused by furring and narrowing of the coronary arteries (heart arteries, 'plumbing of the heart'). Eventually if this is present it can put patients at risk not only of angina chest pains but also of heart attacks. There are a number of different tests that can look at the heart arteries. Traditionally, a test called an invasive coronary angiogram is use to look at the heart arteries (plumbing). This is an accurate and safe test and allows a good look at the heart arteries but has the slight disadvantage that since it is invasive ('invasive' means that it involves tubes being passed from the arm or leg up to the heart), it carries small risks. Hence alternative, non-invasive tests are now also used which are safer and include doing an angiogram instead with a CT scan (CT coronary angiogram) or doing a stress test ('stress' means exercising the heart) whilst having an MRI scan of the heart. The CT coronary angiogram allows us to look at the heart arteries without inserting tubes to the heart and requires just a small needle in the arm through which we inject dye and then take pictures of the heart with the CT scanner (machine like a large polo mint). The CT allows us to take good quality pictures of the heart arteries and with current technology, the radiation levels from modern cardiac CT are low. The stress MRI scan involves giving a safe drug called regadenoson which exercises the heart without you having to physically exercise and then we inject dye through a small needle in the arm to look at the blood flow through the heart arteries into the heart muscle. Where the CT coronary angiogram shows no or only mild narrowings, this suggests that the chest pain unlikely to be due to angina. Where the CT coronary angiogram shows severe narrowing, this suggests that the chest pain may well be due to angina. However it is not uncommon for narrowing to be of moderate/intermediate (medium) severity and in such cases, further tests such as invasive coronary angiograms or stress MRI are needed. There is a new technology available in CT coronary angiography called CT-FFR (CT Fractional Flow Reserve). This uses special software to perform additional measurements of the narrowings in the heart arteries seen on the CT. CT-FFR has the benefit that it requires no increase in time, pictures taken or radiation to the standard CT coronary angiogram for the patient as all the extra calculations are done by a doctor on a computer after the scan is completed. CT-FFR allows us to measure the pressure and therefore blood-flow across a narrowing in an artery to see if the narrowing is actually causing reduced flow (known as angina

or ‘ischaemia’). This could potentially make it very useful for assessing the moderate /intermediate (medium) narrowings to see if they are actually causing angina and hence chest pain. This in turn could potentially prevent patients then needing additional tests such as an invasive coronary angiogram or stress MRI. The aim of this study is to investigate how accurate CT-FFR is at assessing blood flow across narrowings in heart arteries by comparing how closely the findings on CT-FFR agree with those on stress MRI or invasive coronary angiography in order to help patients with narrowed heart arteries in the future and reduce the number of additional tests needed for patients.

Who can participate?
Adults aged 18 and older who are underwent a recent CT coronary angiogram.

What does the study involve?
In this observational study, patients undergo CTCA as the initial investigation of their chest pain to assess for coronary artery disease (CAD). If the referring clinician refers the patient either for a stress CMR or ICA for further assessment for CAD, the participant is invited to join the study. The findings on stress CMR or ICA are compared to those obtained on CT-FFR from CTCA images. The patient's clinical course is unchanged by the study and all analysis are done post-procedure on the routinely-acquired standard images.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
The Royal Liverpool University Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2017 to December 2018

Who is funding the study?
1. Royal Liverpool and Broadgreen University Hospitals NHS Trust (UK)
2. Siemens AG (UK)

Who is the main contact?
Dr Balazs Ruzsics
Dr Jamal Khan

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1

Study information

Scientific Title
Correlation of cardiac CT-FFR (CT-FFR) with stress cardiovascular magnetic resonance (CMR) and invasive diagnostic coronary angiography (ICA) and correlation of cardiac CT-FFR (CT-FFR) and invasive diagnostic coronary angiography (ICA) in patients with coronary artery stents

Study objectives
CT-FFR assessment for ischaemia on coronary CT angiography (CTCA) will correlate closely with assessment for ischaemia on regadenoson stress cardiovascular MRI (stress CMR) and with presence of significant coronary artery disease on invasive coronary angiography (ICA), and in the case of ICA in patients with and without stents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Single-centre observational cohort study assessing correlation between CT-FFR on CTCA with stress CMR and with ICA

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: coronary artery disease

Interventions
Study participants firstly have been seen in a cardiology clinic where it will have been felt that coronary artery disease may be a possible cause of their chest pain, and hence they will undergo a CTCA scan. If their CTCA scan images and findings on standard assessment are such that we feel that further testing in the form of either a non-invasive stress test or invasive coronary angiogram is needed, as per routine this will be indicated on the CTCA. The report goes back to the referring clinician. If the referring clinician then proceeds for the patient to undergo either a stress CMR or invasive coronary angiogram, which based on waiting-lists will be approximately 4-8 weeks after the CTCA, patients are then invited to join the study formally by personally meeting them on the day of their stress CMR or invasive coronary angiogram.

Participants are sent a patient information leaflet by post which arrives with them at least one week before the day of their stress CMR or invasive coronary angiogram so that when we meet them, they are in a position to give informed consent. At that point, the participant enters the trial. Their participation ends on the same day once their stress CMR or invasive coronary angiogram has been performed. If the patient agrees to enter our trial, a CT-FFR analysis on the CTCA images is performed and correlate dwith stress CMR or invasive coronary angiography analysis, which will all be done on the day of the stress CMR or invasive coronary angiogram. There is no participant involvement after this, there is no participant follow-up, there is no participant observation and no change whatsoever to their standard clinical care.

Intervention Type
Other

Primary outcome measure
CT-FFR is measured using the CT-FFR analysis software from CTCA images taken at the patient's CTCA which is their first scan. This is then correlated with either (a) the presence or absence of ischaemia on their subsequent CMR which is assessed on visual analysis of stress perfusion imaging or (b) presence or absence of significant stenosis on their subsequent ICA which is assessed on visual analysis of the ICA images.

Secondary outcome measures

CT-FFR is measured using the CT-FFR analysis software from CTCA images taken at the patient's CTCA which is their first scan and correlated with presence or absence of significant stenosis using standard visual assessment on their CTCA images from the same scan 2. The proportion of coronary artery segments that are deemed on visual analysis of diagnostic, borderline-diagnostic and non-diagnostic quality using CT-FFR assessment and using visual assessment of CTCA images

Overall study start date
01/08/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
Correlation of CT-FFR with stress CMR/ICA:
1. Aged 18 years or more
2. Undergoing CTCA for assessment of stable chest pain due to possible coronary artery disease who then go on to either stress CMR or ICA for further assessment of coronary artery disease reported on CTCA

CT-FFR in coronary artery stented patients
1. Aged 18 or more
3. Coronary artery stent(s) undergoing CTCA for assessment of stable chest pain due to possible coronary artery disease who then go onto ICA for further assessment of coronary artery disease reported on CTCA

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Total 80 (50 in Part A of study and 30 in Part B of study)

Key exclusion criteria
Correlation of CT-FFR with stress CMR/ICA:
1. Aged <18 years
2. Pregnancy
3. CKD with eGFR <30mL/min/1.73m2
4. Claustrophobia precluding CMR
5. Allergy to either iodinated (CT/ICA) or gadolinium based (CMR) contrast
6. Severe airways disease or high-degree heart block (Mobitz II/CHB) precluding regadenoson

/adenosine CMR stress
7. Inability to peripherally cannulate patient for contrast administration
8. Learning difficulties/cognitive impairment precluding informed consent
9. Patient declines participation
10. Patients with stents will be excluded from this component of the study as they will be studied specifically in the second section of the study (below). We will know about the presence of a stent before the CTCA is performed (if referrer informs us or if not, we ask all patients if they have had stent(s)).

CT-FFR in coronary artery stented patients
1. Aged <18 years
2. Pregnancy
3. CKD with eGFR <30mL/min/1.73m2
4. Allergy to iodinated (CT/ICA) contrast
5. Inability to peripherally cannulate patient for contrast administration
6. Learning difficulties/cognitive impairment precluding informed consent
7. Patient declines participation

Date of first enrolment
01/11/2017

Date of final enrolment
01/10/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Liverpool University Hospital
Royal Liverpool and Broadgreen University Hospitals NHS Trust
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Sponsor information

Organisation
Royal Liverpool and Broadgreen University Hospitals NHS Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/009sa0g06

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Liverpool and Broadgreen University Hospitals NHS Trust

Funder Name
Siemens AG

Results and Publications

Publication and dissemination plan
1. National and international conference presentation
2. Publication in medical peer-reviewed journal
Study protocol, patient information leaflet and consent form for the study are available upon request if needed.

Intention to publish date
01/10/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Balazs Ruzsics (balazs.ruzsics@rlbuht.nhs.uk) or Dr Jamal Khan jamal.khan@rlbuht.nhs.uk. These two contacts are the 2 investigators for the study at The Royal Liverpool and Broadgreen University NHS Trust.

IPD sharing plan summary
Available on request