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Cardiac computed tomography (CT) for the Assessment of chest Pain and Plaque

Submission date 25/08/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/09/2010	**Overall study status** Completed	
Last Edited 01/02/2016	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SET/10/52

Study information

Scientific Title
Cardiac computed tomography (CT) for the Assessment of chest Pain and Plaque: a randomised controlled trial

Acronym
CAPP

Study objectives
Background:
Coronary artery disease (CAD) is the leading single cause of death in Europe, accounting for 1.92 million deaths per year, killing approximately 1 in 5 persons. CAD is also the most common cause of premature death in the UK; 19% of premature deaths in men and 10% of premature deaths in women are from CAD. Cardiovascular-related treatment accounts for 18% of overall UK healthcare expenditure. The most common presentation of CAD is angina. Patients "who develop new symptoms which their general practitioner thinks might be due to angina" should be referred to a Rapid Access Chest Pain Clinic (RACPC). Unfortunately, approximately 30% of patients who attend RACPCs are either unsuitable candidates for treadmill or perform a sub-optimal non-diagnostic test. This cohort of patients has been found to have an increased risk of death when compared to those who have a diagnostically positive treadmill test, suggesting they are not adequately served by RACPCs using exercise stress tests (ESTs). A recent multicentre publication prospectively determined that one third of patients attending a RACPC were erroneously diagnosed with non-cardiac chest pain when they were in fact found to fulfil the primary end point criteria of admission to hospital with acute coronary syndrome. This information suggests that patients are not well served by RACPCs. Cardiac computed tomography (CCT) can bridge this gap. The 64-slice scanner has been shown to be an adequate tool for the detection of significant coronary stenoses, and has a high negative predictive value, close to 100 percent in excluding CAD. The effectiveness of CCT has been recognised by a recent NICE document that addressed the issue of patients presenting with chest pain. What is unclear however is how cost effective the use of CCT is, especially taking into account the lack of avail appropriate CCT scanners and as such NICE asked for research into this in a NHS setting.

There is a number of high profile blood biomarkers that have been proven to be of value in predicting the presence of CAD. However these biomarkers are not in widespread use and do not, as yet, have a specific function in clinical practise. We wish to assess a number of biomarkers in comparison to the actual presence of CAD seen on CT. The need for this research is again guided by the NICE document, which also asked for work to be completed into what new circulating biomarkers add to initial assessment of patients with chest pain.

Little is known about the rate at which CAD progresses. Furthermore high profiles studies have shown that statins can cause halt plaque progression. All our patients with CAD will need appropriate secondary prevention (implemented by their GP) and a repeat CT scan after 18 months, in order to reassess their plaque burden and gain information about the rate of disease progression.

Hypothesis:
There will be difference behind the standard of care with EST and that from CCT in terms of patient symptoms and outcome. Data produced from questionnaires, biomarkers, CCT, EST and Intravascular Ultrasound (IVUS). The data will be entered into the clinical trial database and verified for accuracy and completeness. There will be statistical and economical health analysis of the data to try to work out the cost-effectiveness of the two arms.

Ethics approval required
Old ethics approval format

Ethics approval(s)

This will be applied for with Office for Research Ethics Committees Northern Ireland on 28/09 /2010 – submission pending

Study design
Single-centre observational randomised controlled trial

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
Observational Study:
Patients referred to the RACPC in the Ulster Hospital and not excluded by criteria will be considered for the trial. Once in the trial patients will complete questionnaires, have biomarkers taken and be randomised to EST or cardiac CT. The questionnaires to be used will be the established Seattle Angina and EQ-5D questionnaires which, are designed to assess the patients symptoms and their perceived quality of life. They will be repeated at several points, and will not be altered for this study.

The biomarkers to be used include HDL sub-fractions; HS-CRP; Apolipoprotein A-I; Apolipoprotein A-2; Apolipoprotein B; Apolipoprotein(a) precursor (LPA); Homocysteine; HbA1C; Serum Testosterone; Sex hormone-binding globulin (SHBG); Fasting Insulin.; Lipid soluble anti-oxidants; Ascorbic Acid; Lipoprotein and enzyme status; Serum Amyloid A; Cholesterol ester transfer protein; Interleukin-1; Interleukin-6; Interleukin-10; Alpha Tumor necrosis factor; Lipid Hydroperoxide; F2-isoprostanes; Hepatic lipase.

These will be performed to standard NHS/University protocol.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change in scores from baseline at 3 months on the physical limitation scale of the SAQ-UK

Key secondary outcome(s))
1. The cost effectiveness of cardiac CT as a primary diagnostic strategy will be compared with the costs associated with the current standard of care
2. Health-related quality of life
3. Cumulative radiation exposure
4. Resource utilisation

Completion date
01/10/2013

Eligibility

Key inclusion criteria
1. Patients over 40 referred to the Rapid Access Chest Pain Clinic (RACPC), Ulster Hospital, Northern Ireland for suspicion of angina
2. Patients must have the ability to hold breath

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Less than 40 years of age
2. Significant renal dysfunction with an estimated Glomerular Filtration Rate (eGFR) less than 35. As the contrast used in CCT and conventional angiography can cause contrast nephropathy these patients with will be excluded from the study
3. Recent history of alcohol, drug abuse, or other medical conditions that might compromise safety, successful completion of, or drug compliance during the study
4. Patients with a history of chronic inflammatory conditions, such as severe arthritis, lupus, or inflammatory bowel disease, as well as subjects taking immunosuppressant agents, such as cyclosporine, tacrolimus, azathioprine, or chronic oral glucocorticoids. Because High-Sensitivity C-Reactive Protein (hs-CRP) will be measured, patients with other conditions that may cause a chronically elevated CRP will be excluded.
5. Unstable angina pectoris
6. Uncontrolled fast atrial fibrillation or other arrhythmias that may interfere with ECG-gated triggering of CT
7. Patients with extreme tachycardia, greater than 110 bpm, despite rate controlling agents
8. Pregnancy
9. Morbid obesity (Body Mass Index [BMI] >35)
10. Known contrast medium allergy
11. Known ischaemic heart disease with previous intervention in the form of coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI)
12. Inability to lie flat.
13. Severe Aortic Stenosis (clinically suspected and confirmed by echocardiogram)
14. Acute myocarditis/pericarditis
15. Uncontrolled hypertension >220/100
16. Severe peripheral vascular disease or impaired immobility
17. Severe mental disability that would impair capacity to consent
18. Significant COPD that would impair exercise or B blocker use
19. Left bundle branch

Date of first enrolment

01/10/2010

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Ulster Hospital
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Sponsor information

Organisation
Ulster Hospital (UK)

ROR
https://ror.org/04pmdg365

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ulster Hospital (UK) - Research Grant (ref: SET/10/52)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2013		Yes	No
Results article	results	01/04/2015		Yes	No
Results article	results	01/03/2016		Yes	No