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Rapid Assessment of Potential Ischaemic heart Disease with Computed Tomography Coronary Angiography (CTCA)

Submission date
03/10/2014

Recruitment status
No longer recruiting

Registration date
07/10/2014

Overall study status
Completed

Last Edited
06/09/2022

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Recent advances in imaging technology have given us a non-invasive technique called computed tomography coronary angiography (CTCA). However, this technology has not been tested with patients presenting with suspected or confirmed acute coronary syndrome (e.g. heart attack) to the Emergency Department (ED) in the UK. CTCA is capable of giving a better treatment of such patients with suspected or confirmed acute coronary syndrome. This study aims to find out the effect of early CTCA for Emergency Department patients with suspected or confirmed ACS, compared to current standard practice. We also would like to see if this would be cost-effective to the practice.

Who can participate?
All patients aged 18 or over with suspected or confirmed ACS.

What does the study involve?
Eligible participants will be approached in the ED, Medical Assessment Unit (MAU) or Cardiology Unit and asked if they are willing to take part. They will be randomly allocated to CTCA in addition to standard care or standard care alone. During their admission and after 1, 6 and 12 months all participants will be asked to complete questionnaires about their symptoms, quality of life, satisfaction with their care and how often they have had to use healthcare services. Participants will be in the study for one year.

What are the possible benefits and risks of participating?
It is possible that the results of the scan will help your doctor decide whether or not there is any narrowing or blockage of the blood vessels around your heart. It may also show additional unknown problems in the heart and chest that may not have been detected otherwise. The scan can also reveal other potential causes for your chest pain. We hope that the research will also benefit many more people by helping us decide the best way to treat patients with your condition in the future. A CT Coronary Angiogram is a routine medical procedure. The scan itself is associated with very few side effects. The most important potential side effect, as with an x-ray or CT scan, is the use of radiation. The amount of radiation used during the scan varies but is

around two to three times the amount you would normally receive in a year from background natural sources such as cosmic rays. The average excess risk of developing cancer due to a CT scan is 4 in 10,000 compared to a lifetime risk of 1 in 3. There is a very low risk of developing a reaction to the contrast agent. This usually involves an itchy rash that settles down by itself. Occasionally people require additional medications for this. If you are known to have an allergy to the contrast agent you will not be eligible to take part in the study. There is a possibility that the scan could reveal an incidental health problem that you or your doctor is unaware of. If this were to happen we would discuss this with your doctor and arrange appropriate further tests and treatments as necessary.

Where is the study run from?
This study is being co-ordinated by an experienced research team at the University of Edinburgh in collaboration with NHS Lothian. They work closely with doctors and nurses in local research teams in various hospitals throughout the UK.

When is the study starting and how long is it expected to run for?
January 2015 to June 2020 (updated 15/07/2020, previously: December 2018)

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Alasdair Gray
alasdair.gray@nhslothian.scot.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Prof Alasdair Gray

Contact details
EMeRGE Office
Department of Emergency Medicine
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA
+44 (0)131 242 1340
alasdair.gray@nhslothian.scot.nhs.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT02284191

Protocol serial number

HTA 13/04/108

Study information

Scientific Title
The role of early CT Coronary Angiography in the evaluation, intervention and outcome of patients presenting to the Emergency Department with suspected or confirmed acute coronary syndrome

Acronym
RAPID-CTCA

Study objectives
This study aims to investigate the effect of early CTCA for ED patients with suspected or confirmed ACS, compared to current standard practice, upon interventions, event rates and health care costs in a pragmatic clinical trial and economic evaluation up to 1 year after the trial.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1304108
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0007/136996/PRO-13-04-108.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Ethics Committee, 15/12/2014, ref: 14/SS/1096

Primary study design
Interventional

Study design
Open prospective parallel-group randomised controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Emergency/Acute Medicine, Radiology, Cardiology

Interventions
Consented patients will be randomised on a 1:1 basis to CTCA in addition to standard care or standard care alone. All participants will be asked to complete questionnaires at baseline and 1, 6 and 12 months to record QoL, symptoms, patient satisfaction and health services usage.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Current primary outcome measure as of 15/07/2020:
All-cause death or subsequent non-fatal type 1 or type 4b MI at one year, measured as time to first such event. MI will be defined according to the most recent Universal Definition [Thygesen K, 2012] and will be adjudicated by two independent cardiologists blinded to the intervention.

Previous primary outcome measures as of 19/01/2016:
All-cause death or recurrent non-fatal type 1 or type 4b myocardial infarction at one year and time to first such event. Myocardial infarction will be defined according to the most recent Universal Definition [Thygesen K, 2012] and will be adjudicated by two independent cardiologists blinded to the intervention.

Previous primary outcome measures:
All-cause death or recurrent non-fatal type 1 or type 4b myocardial infarction. Myocardial infarction will be defined according to the most recent Universal Definition and will be adjudicated by two independent cardiologists blinded to the intervention.

Key secondary outcome(s)

Current secondary outcome measures as of 15/07/2020:
Key Secondary Endpoints
1. Coronary Heart Disease (CHD) death or subsequent non-fatal MI
2. Cardiovascular Disease (CVD) death or subsequent non-fatal MI
3. Subsequent Non-fatal MI
4. Coronary Heart Disease death
5. Cardiovascular death
6. All-cause death
Other Endpoints
8. Coronary Heart Disease (CHD) death or subsequent non-fatal MI (type 1 or 4b)
9. Subsequent Non-fatal MI (type 1 or 4b)
10. Non-cardiovascular death
11. Invasive coronary angiography
12. Coronary revascularisation
13. Percutaneous coronary intervention
14. Coronary artery bypass graft
15. Proportion of patients prescribed ACS therapies during index hospitalisation
16. Proportion of patients discharged on preventative treatment or have alteration in dosage of preventative treatment during index hospitalisation
17. Length of stay for index hospitalisation
18. Representation or rehospitalisation with suspected ACS/recurrent chest pain within 12 months after index hospitalisation;
19. Chest pain symptoms up to 12 months
20. Patient satisfaction at 1 month
21. Clinician certainty of presenting diagnosis after CTCA
22. Quality of Life (measured by EQ-5D-5L up to12 months)
23. Adverse Events and Serious Adverse Events:
23.1. Proportion of patients with alternative cardiovascular diagnoses identified on CTCA
23.2. Proportion of patients with non-cardiovascular diagnosis identified on CTCA
23.3. Radiation exposure from CTCA as trial intervention
24. Cost effectiveness: estimated in terms of the lifetime incremental cost per quality-adjusted life year (QALY) gained

Previous secondary outcome measures as of 19/01/2016:
1. Hospital length of stay, coronary care length of stay
2. Proportion of patients receiving invasive coronary angiography during index hospitalisation
3. Proportion of patients receiving coronary revascularisation during index hospitalisation
4. Proportion of patients receiving subsequent unplanned coronary revascularisation after index hospitalisation within 12 months
5. Proportion of patients in CTCA arm receiving invasive coronary angiography despite <50% stenosis on CTCA
6. Proportion of patients assigned to CTCA with normal or mild non-obstructive disease
7. Proportion of patients prescribed ACS therapies and/or discharged on secondary prevention treatment or have alteration in dosage of secondary preventive treatment during index hospitalisation
8. Representation or rehospitalisation with suspected ACS/recurrent chest pain within 12 months
9. Patient symptoms and quality of life up to 12 months
10. NHS resource utilisation
11. Patient satisfaction
12. Clinician certainty of presenting diagnosis after CTCA.

Safety:
1. Proportion of patients with allergy/anaphylaxis/acute kidney injury;
2. Proportion of patients with alternative diagnoses that relates to presentation on CTCA e.g. aortic dissection or pulmonary embolus
3. Proportion of patients with incidental finding but potentially concerning on CTCA e.g. malignancy or pulmonary nodules
4. Total average radiation exposure from CTCA in the intervention arm during index hospitalisation.

Cost effectiveness:
Estimated in terms of the lifetime incremental cost per quality-adjusted life year (QALY) gained.

Previous secondary outcome measures:
1. Hospital length of stay, coronary care length of stay
2. Proportion of patients receiving invasive coronary angiography during index hospitalisation
3. Proportion of patients receiving coronary revascularisation during index hospitalisation
4. Proportion of patients receiving subsequent unplanned coronary revascularisation after index hospitalisation within 12 months
5. Proportion of patients in CTCA arm receiving invasive coronary angiography despite <50% stenosis on CTCA
6. Proportion of patients assigned to CTCA with normal or non-diagnostic imaging
7. Proportion of patients prescribed ACS therapies and/or discharged on secondary prevention treatment during index hospitalisation
8. Representation or rehospitalisation with suspected ACS/recurrent chest pain within 12 months
9. Patient symptoms and quality of life up to 12 months
10. NHS resource utilisation
11. Patient satisfaction

Safety:
1. Proportion of patients with allergy/anaphylaxis/acute kidney injury
2. Proportion of patients with alternative diagnoses e.g. aortic dissection or incidental but potentially concerning e.g. malignancy or pulmonary nodules
3. Total radiation exposure in each arm

Cost effectiveness:
Estimated in terms of the lifetime incremental cost per quality-adjusted life year (QALY) gained

Completion date
30/06/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/01/2016:
Patients ≥18 years with symptoms mandating investigation for suspected or confirmed ACS with at least one of:
1. ECG abnormalities e.g. ST segment depression >0.5 mm
2. History of ischaemic heart disease (where the clinician assessing patient confirms history based on patient history or available records)
3. Troponin elevation above the 99th centile of the normal reference range or increase in high sensitivity troponin meeting European Society of Cardiology criteria for 'rule-in' or myocardial infarction
(NB troponin assays will vary from site to site; local laboratory reference standards will be used).

Previous inclusion criteria:
Patients aged 18 years or older with symptoms mandating investigation for suspected or confirmed ACS with at least one of:
1. ECG abnormalities e.g. ST segment depression >0.5 mm
2. History of ischaemic heart disease
3. Troponin elevation above the 99th centile of the normal reference range
(NB troponin assays will vary from site to site; local laboratory reference standards will be used).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
1748

Key exclusion criteria
Current exclusion criteria as of 19/01/2016:
1. Signs, symptoms, or investigations supporting high-risk ACS:
1.1. ST elevation MI

1.2. ACS with signs or symptoms of acute heart failure or circulatory shock
1.3. Crescendo episodes of typical anginal pain
1.4. Marked or dynamic ECG changes e.g. ST depression of >3 mm
1.5. Clinical team have scheduled early invasive coronary angiography on day of trial eligibility assessment
2. Patient inability to undergo CT:
2.1. Severe renal failure (serum creatinine >250 µmol/L or estimated glomerular filtration rate <30 mL/min)
2.2. Contrast allergy
2.3. Beta blocker intolerance (if no alternative heart rate limiting agent available/suitable) or allergy
2.4. Inability to breath hold
2.5. Atrial fibrillation (where mean heart rate is anticipated to be greater than 75 beats per minute after beta blockade)
3. Patient has had invasive coronary angiography or CTCA within last 2 years and the previous investigation revealed obstructive coronary artery disease, or patient had either investigation within the last 5 years and the result was normal
4. Previous recruitment to the trial
5. Known pregnancy or currently breastfeeding
6. Inability to consent
7. Further investigation for ACS would not in the patient's interest, due to limited life expectancy, quality of life or functional status
8. Prisoners

Previous exclusion criteria:
1. Signs, symptoms, or investigations supporting high-risk ACS: ST elevation MI; ACS with signs or symptoms of acute heart failure or circulatory shock; Crescendo episodes of typical anginal pain; marked or dynamic ECG changes e.g. ST depression of >3 mm
2. Patient inability to undergo CT: severe renal failure (serum creatinine >250 µmol/L or estimated glomerular filtration rate <30 mL/min); contrast allergy; beta blocker intolerance; inability to hold breath; atrial fibrillation (mean heart rate greater than 75 beats per minute)
3. Invasive coronary angiography or CTCA within last 2 years if the previous investigation revealed CAD, 5 years if previous investigation normal
4. Previous recruitment to the trial
5. Known pregnancy
6. Inability to consent
7. Further investigation for ACS would not in the patients interest, due to limited life expectancy, quality of life or functional status
8. Prisoners

Date of first enrolment
11/03/2015

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Jersey

Study participating centre
Royal Infirmary of Edinburgh
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Sheffield Northern General Hospital
Sheffield
United Kingdom
S5 7AU

Study participating centre
Plymouth Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Torbay Hospital
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Victoria Hospital
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
Russells Hall Hospital
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Royal Berkshire NHS Foundation Trust
Reading
United Kingdom
RG1 5AN

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Royal Bournemouth Hospital
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
Jersey General Hospital
Saint Helier
Jersey
JE1 3QS

Study participating centre
Borders General
Melrose
United Kingdom
TD6 9BS

Study participating centre
Royal Victoria Infirmary
Newcastle

United Kingdom
NE7 7DN

Study participating centre
Lewisham University Hospital
London
United Kingdom
SE13 6LH

Study participating centre
Glasgow Royal Infirmary
Glasgow
United Kingdom
G4 0SF

Study participating centre
Milton Keynes Hospital NHS Foundation Trust
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
University Hospitals of the North Midlands (UHNM)
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Sandwell General Hospital
West Bromwich
United Kingdom
B71 4HJ

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
London
United Kingdom
SE1 7EH

Study participating centre
Rotherham General Hospital
Rotherham
United Kingdom
S60 2UD

Study participating centre
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Study participating centre
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Study participating centre
Surrey & Sussex Hospitals (East Surrey Hospital)
Redhill
United Kingdom
RH1 5RH

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton
United Kingdom
SO16 6YD

Study participating centre
Manchester University NHS Foundation Trust (MFT)
Manchester
United Kingdom
M23 9LT

Study participating centre

Luton and Dunstable University Hospital
Luton
United Kingdom
LU4 0DZ

Study participating centre
Barts Health NHS Trust Royal London Hospital
London
United Kingdom
EC1A 7BE

Study participating centre
Whipps Cross University Hospital
London
United Kingdom
E11 1NR

Study participating centre
Worcestershire Acute Hospitals NHS Trust
Worcester
United Kingdom
WR5 1DD

Study participating centre
Ulster Hospital
Belfast
United Kingdom
BT16 1RH

Study participating centre
University Hospital North Tees
Stockton-on-Tees
United Kingdom
TS19 8PE

Study participating centre

Ninewells Hospital, NHS Tayside
Dundee
United Kingdom
DD1 9SY

Study participating centre
Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Betsi Cadwaladr University Health Board (Wrexham Maelor Hospital)
Wrexham
United Kingdom
LL13 7TD

Study participating centre
Basildon and Thurrock University Hospitals NHS Foundation Trust
Basildon
United Kingdom
SS16 5NL

Study participating centre
The Royal Wolverhampton NHS Trust
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Raigmore Hospital
Inverness
United Kingdom
IV2 3UJ

Study participating centre

Queen Elizabeth University Hospital
Glasgow
United Kingdom
G51 4TF

Sponsor information

Organisation
The University of Edinburgh (UK)

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme (Ref: 13/04/108)

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/09/2021	04/10/2021	Yes	No
Results article	HTA report	01/08/2022	06/09/2022	Yes	No
Protocol article	protocol	07/12/2016		Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes