

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

<b>Submission date</b> 03/10/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/09/2022	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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

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## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Alasdair Gray

**Contact details**

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## Additional identifiers

**ClinicalTrials.gov (NCT)**

NCT02284191

**Protocol serial number**

## 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](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

### Study design

Open prospective parallel-group randomised controlled trial

### Primary study design

Interventional

### 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 to 12 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  $\geq 18$  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/01nrxf90>

## 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?
<a href="#">Results article</a>	results	29/09/2021	04/10/2021	Yes	No
<a href="#">Results article</a>	HTA report	01/08/2022	06/09/2022	Yes	No
<a href="#">Protocol article</a>	protocol	07/12/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes