RAPID-CTCA TRIAL: SUMMARY & GUIDE TO SITE SET UP

Aims
This study aims to investigate the effect of early computed tomography coronary angiography (CTCA) in patients with suspected or confirmed ACS upon interventions, event rates and health care costs in a pragmatic clinical trial. The primary objective will be to investigate the effect of the intervention on the proportion of patients with all-cause death or recurrent non-fatal Myocardial Infarction at one year.

Design
An open, prospective, parallel-group, randomised controlled trial of CTCA in patients presenting to the Emergency Department or Medical Assessment Unit with suspected or confirmed acute coronary syndrome (ACS).

Site Eligibility
We are looking for 30 NHS tertiary and district hospitals with emergency departments, acute medical, and radiology and cardiology services. Radiology needs the capacity to perform on average one research cardiac scan per week.

Inclusion criteria
Patients ≥18 years with suspected/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.

Exclusion criteria:
1. Signs/symptoms/investigations supporting high-risk ACS: ST elevation MI; ACS with signs/symptoms of acute heart failure/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; contrast allergy; beta-blocker intolerance; atrial fibrillation;
3. Invasive coronary angiography/CTCA within the last 2 years if patient has coronary artery disease and 5 years if CTCA 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 be in the patient's interest
8. Prisoners

SITE SET-UP GUIDE

- Request Site Selection Questionnaire from rapid.ctca@ed.ac.uk, complete and return to same address. KEY CONTACTS – Local PI, R&D
- Arrange and meet with all specialties who will be involved in the trial locally and establish working practices for participation in the trial, ensuring agreement from radiology and that there is scan availability. KEY CONTACT- Local PI.
- Discuss your potential participation with the R&D department and inform them that there are Excess Treatment Costs associated with this study. Provide an R&D contact to the rapid.ctca@ed.ac.uk to follow this up. KEY CONTACTS: Local PI/Trial Manager/R&D
- Template Site Agreement to be sent to the local contracts team to populate basic details and provide any comments. KEY CONTACTS: Local contracts team/Trial Manager.
- A template SSI form can be transferred by the Trial Manager to the site for completion. This will need to be submitted for R&D review. KEY CONTACTS- PI/R&D/Trial Manager.
- A Site Initiation Visit date should be arranged and a potential start date decided. PI/Research Nurse to provide dates to Trial Manager.
- R&D will complete review and provide approval. KEY CONTACT- R&D
- Confirm start date which should be known at time of the SIV. 'Green light' will be given by the trials team to start work on the project once the SIV has been completed and all essential components are in place.
- 1st participant should be recruited within 30 days of R&D approval.

For any questions please contact the Kat Oatey at rapid.ctca@ed.ac.uk or telephone 0131 537 3841 or 0131 242 3687.

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