

Project Title:	Complete Versus Lesion-only PRimary PCI pilot -Cardiac MRI substudy (CVLPRI-t-CMR)
Project Ref:	10/27/01
Cost:	£378,273
Lead Applicant & Institution:	Dr Gerald McCann Consultant Cardiologist University Hospitals of Leicester NHS Trust
Start Date:	01 November 2010
Plain English Summary:	<p>Heart attacks are usually caused by blood clots forming in narrowed heart arteries. Patients having heart attacks are increasingly treated with balloons and stents to open their blocked arteries. If they have an important narrowing in another artery in addition to their blocked artery it can be difficult to decide whether this other narrowing should be treated at the same time as the blockage causing the heart attack. There are no definitive studies to tell heart specialists what to do for the best. This study will randomize such patients into two groups. One group will have both the blocked (heart attack- causing) artery plus the other incidentally narrowed artery treated at the same time or during their initial hospital admission and the second group will have only the blocked artery treated. This study will assess which treatment strategy- stents to all the narrowed arteries or only the blocked artery- is associated with the least damage to the heart muscle, which will go on to form a scar. The more heart muscle that is replaced by scar the less well the heart is able to pump and the higher the risk of further serious complications such as heart failure and sudden death. The results will help inform heart specialists how best to treat tens of thousands of patients presenting each year in the UK with heart attacks.</p> <p>The researchers comprise heart specialists with expertise in stenting, MRI and running clinical research studies. The major cost of this study is related to measuring the amount of heart scar with a new technique using MRI scans. MRI scans give very accurate measures of the amount of scar and how well the heart is able to pump following a heart attack. The main ethical issue the researchers face is obtaining 'informed' consent for the study from patients in the midst of a heart attack and when prompt treatment is critical. Patients will be asked to give 'assent' to the study after reading a shortened consent form before the first stent procedure. They will then be asked to confirm their continued participation in the study (including the MRI scans) the day following their heart attack and after reading all the patient information sheets. Such a strategy has been used successfully for other new treatments for heart attack patients.</p>
Abstract:	DESIGN: CVLPRI-t: Multi-centre, open, pilot, randomized, controlled clinical trial. CVLPRI-t-CMR: + blinded endpoint analysis

	<p>POPULATION: 250 patients with ST elevation myocardial infarction(MI) undergoing primary percutaneous angioplasty (P-PCI) with multi-vessel coronary artery disease.</p> <p>INTERVENTION: Complete in-hospital revascularisation with PCI (infarct-related artery and major coronary vessels (> 2.0mm) with severe stenosis) and optimal medical therapy (OMT).</p> <p>COMPARATOR: Infarct related P-PCI only with OMT. Further revascularisation for refractory angina despite OMT or ischaemic burden >20% of total myocardium on non-invasive imaging.</p> <p>OUTCOME MEASURES: Main CULPRIT study: Major adverse cardiac events: all-cause death, recurrent MI, heart failure, need for revascularization (PCI or CABG) at 12 months</p> <p>CMR substudy (BLINDED ENDPOINTS) Primary: 1. MI size (% of LV mass) on pre-discharge CMR. Secondary: 1. Myocardial salvage index, extent of microvascular obstruction, ejection fraction (EF) and left ventricular(LV) end diastolic(EDV) and systolic volumes(ESV), pre-discharge CMR. 2. LVEDV, ESV, EF and ischaemic burden on CMR at 9 months.</p> <p>ASSESSMENT AND FOLLOW-UP: CMR will be performed pre-discharge (1-4 days) post MI and at 9 months. Clinical assessments for MACE at 3,6, 9 and 12 months (endpoints).</p> <p>PROPOSED SAMPLE SIZE: It is anticipated the main study will recruit in total 250 patients. For the CMR study it is likely not all will be eligible/consent to CMR. 100 patients in each arm has 80% power to detect an absolute 4% difference in infarct size assuming infarct size 20 (10)% of LV mass, in culprit-only revascularisation, alpha=0.05 and 2-tailed.</p> <p>STATISTICAL ANALYSIS: Analysis will be performed by a statistician from the CTEU at the Royal Brompton Hospital (supported by Imperial CTEU). Groups will be compared by 2 sample t-tests/Fisher's exact test and Chi-square as appropriate and will be by intention to treat. Event free survival will be assessed by Kaplan-Meier curves. Univariate predictors of outcome will be assessed by logistic regression analysis and independent predictors by multivariate analysis. The trial will be overseen by a trial steering committee and an independent data and safety monitoring board with planned sub group analysis when 60 patients in each arm have been recruited.</p>
ISRCTN: (if applicable)	
Project Protocol:	www.eme.ac.uk/projectfiles/102701protocol.pdf
Project website: (if applicable)	To follow
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