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Counterpulsation to Reduce Infarct Size pre-percutaneous coronary intervention (pre-PCI) for Acute Myocardial Infarction

Submission date 05/12/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/12/2008	**Overall study status** Completed	
Last Edited 28/08/2013	**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

ClinicalTrials.gov (NCT)
NCT00833612

Protocol serial number
00001

Study information

Scientific Title

A multi-centre, randomised controlled study of mechanical left ventricular unloading with counterpulsation to reduce infarct size pre-percutaneous coronary intervention (pre-PCI) for acute myocardial infarction

Acronym
CRISP-AMI

Study objectives
The purpose of this study is to examine whether the use of an intra-aortic balloon (IAB) pump is beneficial for patients having a heart attack before the angioplasty procedure. Subjects with anterior acute ST-segment elevation myocardial infarction (STEMI) who receive an IAB before primary percutaneous coronary intervention (PCI) will have decreased anterior myocardial infarction (MI) size.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre, randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute myocardial infarction

Interventions
Patients will be randomised to recieve an intra-aortic balloon prior to primary percutaneous coronary intervention. The control group will be those patients randomised not to receive an intra-aortic balloon prior to their primary percutaneous coronary intervention.

For subjects randomised to receive IABC, the balloon will be removed on the day following the procedure if the subject is haemodynamically stable. Twenty-four to 48 hours is the optimal length of time for the subject to use the balloon, with a minimum time of 12 hours. All patients will be followed up at 3 months and 6 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Infarct size measured by MRI at 3 to 5 days post-PCI or at discharge, whichever comes first. The primary analysis population will be restricted to the subgroup of subjects with nondistal left

anterior descending (LAD) lesion and thrombolysis in myocardial infarction (TIMI) flow of 0 or 1.
2. Other efficacy endpoints of importance:
2.1. Left ventricular ejection fraction (LVEF)
2.2. Microvascular obstruction (MVO) by MRI
2.3. Electrocardiogram (ECG) ST-segment resolution 90 minutes post-PCI
2.4. Left ventricular end-diastolic volume (LVEDV)
2.5. Left ventricular end-systolic volume (LVESV)
2.6. Salvage index by MRI

Key secondary outcome(s))
1. Vascular complications, defined as major limb ischaemia requiring operative intervention in the affected IAB limb after removal of the IAB
2. Amputation
3. Major bleed per GUSTO I definition, i.e., intracranial haemorrhage or bleeding that causes haemodynamic compromise and requires intervention
4. Major adverse cardiac events (MACE) within 24 hours of hospital admission, including:
4.1. Ventricular arrhythmias: VT, VF
4.2. Severe hypotension: systolic blood pressure (SBP) less than 90 mmHg for more than or equal to 5 minutes, requiring inotropic/pressor support medications or IV fluid
4.3. Cardiac arrest

Completion date
31/12/2009

Eligibility

Key inclusion criteria
To be eligible for this study, a subject must meet all of the following criteria:
1. Able to understand and sign an informed consent form (ICF)
2. Greater than or equal to 18 and less than or equal to 90 years of age, either sex
3. General good health, in the opinion of the investigator
4. ST elevation of greater than or equal to 2 mm in two contiguous anterior leads or greater than or equal to 4 mm total in anterior leads
5. Scheduled for PCI less than 6 hours from onset of symptoms of anterior MI

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Key exclusion criteria
A subject who meets any of the following exclusion criteria will not be enrolled in the study:
1. Known contraindication to magnetic resonance imaging (MRI)
2. Prior thrombolytic therapy during the index event
3. Known history of MI
4. Prior coronary artery bypass graft surgery
5. Known severe aortic insufficiency
6. Known aortic aneurysm
7. Known severe calcific aorta-iliac disease or peripheral vascular disease
8. Experiencing cardiogenic shock
9. Known end-stage renal disease
10. Weight greater than 400 lbs or height less than 4 feet
11. Women of childbearing potential

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
United Kingdom

Belgium

France

Germany

Ireland

Italy

United States of America

Study participating centre
Duke University Medical Centre
Durham, North Carolina
United States of America
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Sponsor information

Organisation
Datascope Corp. (USA)

ROR
https://ror.org/05pwp0t27

Funder(s)

Funder type
Industry

Funder Name
Datascope Corp. (USA)

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	28/09/2011		Yes	No