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Balloon pump assisted Coronary Intervention Study

Submission date	Recruitment status	[_] Prospectively registered
13/09/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/06/2023	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00910481

Secondary identifying numbers
N/A

Study information

Scientific Title
Balloon pump assisted Coronary Intervention Study

Acronym
BCIS-1

Study objectives
Elective use of Intra-Aortic Balloon Pump (IABP) in high risk Percutaneous Coronary Intervention (PCI) patients will reduce the rate of in-hospital major adverse cardiovascular events compared to patients who are managed with no planned insertion of IABP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the UK MREC for Scotland on the 28th April 2005 (ref. no.: 05/MRE00 /43).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Multi-vessel coronary artery disease

Interventions
In brief patients in the elective group will have the IABP inserted at the start of the procedure, before coronary intervention. Unless prolonged use is clinically indicated, the IABP will be removed four to 24 hours following PCI. An intravenous (iv) heparin infusion will be commenced on completion of the Abciximab infusion, with a target Activited Partial Thromboplastin Time (APTT) ratio between 1.5 and 2.5. When it is felt appropriate to remove the IABP, the heparin infusion will be discontinued and the balloon catheter removed when the Activated Clotting Time (ACT) falls below 160 seconds. Manual pressure haemostasis is recommended.

In the No Planned group, bailout IABP insertion is at the discretion of the operator and would be considered acceptable if the following conditions occur during PCI:

1. Prolonged hypotension (relative to initial BP)
2. Refractory VT/VF
3. Pulmonary oedema

Bailout IABP insertion will be recorded as a secondary outcome event and not as cross-over between treatment assignments, if inserted in the context of the above conditions.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Balloon pump

Primary outcome measure
Comparison of Major Adverse Cardiovascular Events (MACE) at hospital discharge or 28 days whichever is sooner. MACE includes death, myocardial infarction, cerebrovascular accident and repeat revascularisation.

Secondary outcome measures
1. Mortality at six months
2. Procedural success
3. Procedural complications
4. Bleeding complications
5. Access site complications
6. Transient ischaemic attacks
7. Length of hospital stay

Overall study start date
01/12/2005

Completion date
30/07/2006

Eligibility

Key inclusion criteria
1. Patients at least 18 years of age
2. Proposed single or multi-vessel percutaneous intervention to native coronary arteries or coronary bypass grafts
3. Presence of BOTH the following high risk features:
3.1. Impaired Left Ventricular (LV) function: Ejection Fraction (EF) less than 30% (quantified by echocardiography or LV angiography)
3.2. Large area of myocardium at risk, either unprotected left main stem target lesion or Jeopardy Score more than or equal to eight, or target vessel provides collateral supply to an

occluded second vessel which supplies more than 40% of myocardium
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Shock (systolic Blood Pressure [BP] less than 85 mmHg despite correction of hypovolaemia)
2. Acute myocardial infarction within previous 48 hours defined as:
2.1. chest pain or equivalent symptoms consistent with acute myocardial infarction, and
2.2. New ST segment elevation of at least 1 mm in two or more contiguous Electrocardiogram (ECG) leads, persisting for more than 15 minutes, or new left bundle branch block on ECG persisting for more than 15 minutes
3. Planned staged intervention procedure within 28 days of index PCI
4. Ventricular Septal Defect (VSD)/Mitral Regurgitation (MR) or intractable Ventricular Tachycardia and Ventricular Fibrillation (VT/VF) post Myocardial Infarction (MI)
5. Thoracic/abdominal aortic disease
6. Significant ilio-femoral artery disease (documented on Doppler studies or ilio-femoral angiography or absent femoral pulses bilaterally), the presence of clinical signs of acute leg ischaemia and previous bilateral femoral bypass graft surgery
7. More than mild aortic regurgitation on echocardiography
8. Bleeding diathesis or Warfarin therapy with International Normalised Ratio (INR) more than 2.5
9. Active internal bleeding (except menstruation)
10. Allergy to aspirin, clopidogrel, heparin or Glycoprotein (GP) IIb/IIIa inhibitors
11. Thrombocytopenia (platelet count less than 100,000 cells/mm^3)
12. Women who are pregnant
13. Patients who have previously been enrolled in this study

Date of first enrolment
01/12/2005

Date of final enrolment
30/07/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool Cardiothoracic Centre
Liverpool
United Kingdom
L14 3PE

Sponsor information

Organisation
British Cardiovascular Intervention Society

Sponsor details
Kings College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Sponsor type
Research organisation

Website
http://www.bcis.org.uk/

ROR
https://ror.org/03dnhfz27

Funder(s)

Funder type
Industry

Funder Name
Datascope (UK)

Funder Name
Cordis - a Johnson and Johnson Company (UK)

Funder Name
Eli Lilly and Company Limited (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2009		Yes	No
Results article	results	25/08/2010		Yes	No
Results article	results	15/01/2013		Yes	No