

Balloon pump assisted Coronary Intervention Study

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Rodney Stables

Contact details
Liverpool Cardiothoracic Centre
Thomas Drive
Liverpool
United Kingdom
L14 3PE

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00910481

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).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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 Activated 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

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Balloon pump

Primary outcome(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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/mm³)
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

United Kingdom

England

Study participating centre

Liverpool Cardiothoracic Centre

Liverpool

United Kingdom

L14 3PE

Sponsor information

Organisation

British Cardiovascular Intervention Society

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

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?
Results article	results	25/08/2010		Yes	No
Results article	results	15/01/2013		Yes	No
Protocol article	protocol	01/12/2009		Yes	No