# Balloon pump assisted Coronary Intervention Study

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

# 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

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