

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

<b>Submission date</b> 05/12/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/08/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**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**  
NCT00833612

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Acute myocardial infarction

## Interventions

Patients will be randomised to receive 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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/01/2009

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

90 Years

**Sex**

Both

**Target number of participants**

300

**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**

Belgium

France

Germany

Ireland

Italy

United Kingdom

United States of America

**Study participating centre**  
**Duke University Medical Centre**  
Durham, North Carolina  
United States of America  
27710

## Sponsor information

### Organisation

Datascope Corp. (USA)

### Sponsor details

c/o Debra Joseph  
15 Law Drive  
Fairfield, New Jersey  
United States of America  
07004

### Sponsor type

Industry

### Website

<http://www.datascope.com>

### ROR

<https://ror.org/05pwp0t27>

## Funder(s)

### Funder type

Industry

### Funder Name

Datascope Corp. (USA)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
<a href="#">Results article</a>	results	28/09/2011		Yes	No