

# Point of care platelet activity measurement in Primary Percutaneous Coronary Intervention (PPCI)

<b>Submission date</b> 22/03/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/06/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/11/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

An ST segment Elevation Myocardial Infarction (STEMI) is a heart attack caused by a completely blocked blood vessel. Heart attacks are increasingly being treated by re-opening the blocked heart artery and placing a metal-mesh tube (stent). This is called primary percutaneous coronary intervention or PPCI. In addition to scaffolding the artery with a stent, drugs are used to thin the patient's blood. We have recently changed the drugs given to patients presenting to the Bristol Heart Institute with heart attacks. The drugs we have selected are potent blood thinners and have been shown to act very fast. We will describe the relationship between blood thinning at the end of the procedure with the time given for the drug to take effect, and ultimately with side effects developed within the first 30 days after stenting.

### Who can participate?

Patients aged 18 and over with an acute STEMI (heart attack) and undergoing PPCI.

### What does the study involve?

The patients' blood clotting ability is assessed on arrival at the hospital, at the completion of the PPCI, and at 1, 2 and 24 hours after the completion of the PPCI. This is a simple blood test, taking 3 ml of blood at each time, a total of 15 ml of blood. Following the procedure, patients are usually transferred to the coronary care unit (CCU), where they receive further drug treatment, undergo an echocardiogram (heart scan), and contact is made with the cardiac rehabilitation team. Ideally, patients transfer from the CCU to a cardiology ward after 24 hours and discharge is arranged from 48 hours onwards. All patients are invited to a clinic 1 month later. At this appointment any ongoing symptoms/problems are assessed, a 12-lead ECG is undertaken (recording the heart's electrical activity), and a clinical examination is performed, including weight, height, heart rate and blood pressure. Where necessary, the patients' medication is adjusted and further investigations are arranged for ongoing care.

### What are the possible benefits and risks of participating?

This is an observational study so there are no benefits or risks of participating.

Where is the study run from?  
Bristol Heart Institute at the Bristol Royal Infirmary (UK).

When is the study starting and how long is it expected to run for?  
March 2011 to October 2012.

Who is funding the study?  
The study is funded from Above and Beyond Project 353.

Who is the main contact?  
Dr Thomas Johnson  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
10/H0106/87

## Study information

**Scientific Title**  
A study of Platelet INhibition using a 'POINT of care' platelet function test, following Primary Percutaneous Coronary Intervention for ST elevation myocardial infarction (PINPOINT-PPCI)

**Acronym**  
PINPOINT-PPCI

## **Study objectives**

Minimising the time from STEMI symptom onset to definitive treatment, with mechanical revascularisation, remains a major focus of attention in optimising the PPCI service. We hypothesise that continued reductions in the 'door to balloon' time (time from hospital admission to achieving an open artery in the catheter laboratory) may result in some patients undergoing PPCI with incomplete P2Y12 blockade, leading to an increase in risk of early thrombotic events. We speculate that the rapid restoration of coronary flow achieved with PPCI may offer inadequate time to achieve platelet inhibition with prasugrel, prior to the loss of the anti-thrombin effect of bivalirudin.

The primary objective of the study is to describe variation in platelet activity at the end of the PPCI and to quantify the relationship between 'door to balloon time' and platelet function in the first 24 hours after completing the PPCI.

The secondary objective of the study is to test the hypothesis that patients with high platelet activity at the time of arrival at hospital (baseline) achieve less platelet inhibition in the first 24 hours following commencement of anti-thrombotic and anti-platelet therapy.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

NRES Committee South West - Frenchay, ref: 11/SW/0024

## **Study design**

Prospective observational study

## **Primary study design**

Observational

## **Secondary study design**

## **Study setting(s)**

Hospital

## **Study type(s)**

Diagnostic

## **Participant information sheet**

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

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

ST elevation myocardial infarction

## **Interventions**

Platelet function (measured in peripheral 'whole' blood) will be assessed on arrival at hospital, at completion of the PPCI, 1, 2 and 24 hours after the completion of the PPCI. These measurements will allow the study to test how the profile of platelet function changes over the period of time in which the effect of bivalirudin wanes and prasugrel increases, by assessing the interaction between door-to-balloon time and time-after-completion of PPCI. This is a simple blood test -

taking 3ml of venous blood at each time interval - a total of 15ml of blood, where only one time point involves venapuncture, as all other time points, clinical routine bloods are taken. The trial also involves a 30 day follow appointment. Following the procedure, patients are usually transferred to the coronary care unit (CCU).

Secondary preventative treatment, including beta-blockade, angiotensin-converting-enzyme (ACE) inhibition, and statin therapy, is commenced during the in-patient stay, an echocardiographic assessment of left ventricular function is obtained and contact is made with the cardiac rehabilitation team. Ideally, patients transfer from CCU to a cardiology ward at 24hrs and discharge is arranged from 48hours onwards.

All patients undergoing PPCI are invited to a specialised clinic at 1 month. At this appointment any ongoing symptoms/problems are assessed, a 12-lead ECG is undertaken, and a clinical examination including weight, height, heart rate, and blood pressure is performed. Where necessary, medication is up-titrated and further investigations are arranged for ongoing care.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

1. The platelet function assessment measured in peripheral whole blood
2. Functional assessment of Adenosine diphosphate (ADP) receptor, arachidonic acid pathway, and thrombin related platelet activation will be measured using a multiple electrode analyser (MEA - Multiplate platelet function analysis)

Platelet function (measured in peripheral 'whole' blood, see above) will be assessed on arrival at hospital, at completion of the PPCI, 1, 2 and 24 hours after the completion of the PPCI. These measurements will allow the study to test how the profile of platelet function changes over the period of time in which the effect of bivalirudin wanes and prasugrel increases, by assessing the interaction between door-to-balloon time and time-after-completion of PPCI.

### **Secondary outcome measures**

Incidence of adverse clinical events at 24hours and 30days, including:

1. Major adverse cardiac events (MACE) - a composite of target vessel revascularisation, target lesion revascularisation, non-fatal myocardial infarction, and cardiac death
2. Bleeding complications - using Thrombolysis In Myocardial Infarction (TIMI) major and minor bleeding criteria
3. Stent thrombosis [Academic Research Consortium (ARC) definition]

### **Overall study start date**

17/03/2011

### **Completion date**

31/10/2012

## **Eligibility**

### **Key inclusion criteria**

A participant may enter the study if ALL of the following apply:

1. Admitted with acute ST elevation myocardial infarction (STEMI)
2. Treated with PPCI at the time of index procedure

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

108

**Key exclusion criteria**

A participant may not enter the study if ANY of the following apply:

1. Unable to take prasugrel
2. Unable to take bivalirudin
3. Haemodynamic instability/cardiogenic shock
4. Current treatment with clopidogrel or prasugrel

**Date of first enrolment**

17/03/2011

**Date of final enrolment**

31/10/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Bristol Heart Institute**

Bristol

United Kingdom

BS2 8HW

## **Sponsor information**

**Organisation**

University Hospitals Bristol NHS Foundation Trust (UK)

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.uhbristol.nhs.uk/research-innovation/how-to-contact-us/>

### **ROR**

<https://ror.org/04nm1cv11>

## **Funder(s)**

### **Funder type**

Charity

### **Funder Name**

Above & Beyond (UK) (Project 353)

## **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="#">Protocol article</a>	protocol	04/04/2014		Yes	No

[Results article](#)

results

16/12/2015

Yes

No