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

Submission date
22/03/2012

Recruitment status
No longer recruiting

Registration date
07/06/2012

Overall study status
Completed

Last Edited
22/11/2018

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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.

Key secondary outcome(s))
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]

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Bristol Heart Institute
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Charity

Funder Name
Above & Beyond (UK) (Project 353)

Results and Publications

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?
Results article	results	16/12/2015		Yes	No
Protocol article	protocol	04/04/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes