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A study assessing the usefulness of measuring platelet function after cardiac surgery

Submission date
11/01/2014

Recruitment status
No longer recruiting

Registration date
23/01/2014

Overall study status
Completed

Last Edited
09/09/2015

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients suffering from a type of heart disease called coronary artery disease (CAD) are treated with drugs like Aspirin and Clopidogrel. When they come for coronary artery bypass surgery (CABG) these medications are usually stopped a few days before surgery to reduce bleeding after the operation (postoperative bleeding). However, stopping the medications has some risks and hence it is often continued until the day of surgery. Patients who are still on medication are at an increased risk of postoperative bleeding. Transfusion of blood and blood products can have harmful effects and hence efforts should be made to minimize transfusion. There is a need to test for platelet dysfunction before platelet transfusion. Several platelet function tests have been reported to measure platelet dysfunction and find out if there is a need for platelet transfusion. However, none of these tests are suitable for routine clinical practice as they are laborious and time consuming. We aim to design a study to compare the accuracy of two tests, thromboelastography (TEG) and Multiplate® analyzer, and to determine their usefulness in prediction of postoperative blood loss and in guiding postoperative transfusion requirements (blood and platelets) and the need for surgical re-exploration.

Who can participate?
Patients referred for first time isolated CABG will be approached to take part in the study.

What does the study involve?
Group A will include patients who were on anti-platelet drugs till the day of surgery. Group B will include who stopped anti-platelet drugs at least 5 days before the operation. Blood was sampled for Multiplate® and TEG assessments immediately after inserting the arterial line (before the operation) and after protamine administration after cessation of cardiopulmonary bypass (after the operation). We will compare the two groups' post-surgery blood loss and need for transfusion of blood products after the operation. TEG and Multiplate® analyzer results will also be compared for the two groups. No additional clinical visits will be required for the purpose of the study.

What are the possible benefits and risks of participating?
There are no direct benefits to the patients enrolled in this study. It will improve our understanding of the effect of antiplatelet drugs and will compare the two tests: TEG and

Multiplate®. The results of this study can be of potential benefit to future patients. Patients enrolled for the study will be treated according to routine during and after the operation. The only additional intervention will be blood sampling. The study itself will not cause any adverse event.

Where is the study run from?
The Heart and Lung Centre, Wolverhampton, UK.

When is the study starting and how long is it expected to run for?
The study started in November 2011 and ended in June 2013.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Protocol Version 3 (Date 3th Aug 2011) R&D number 10CARD16

Study information

Scientific Title
The role of point-of-care assessment of platelet function in predicting postoperative bleeding and transfusion requirements after coronary artery bypass grafting (CABG)

Study objectives
Objective measurement of platelet function after cardiac surgery can be potentially useful in prediction of postoperative blood loss and in guiding postoperative transfusion requirements (blood and platelets) and the need for surgical re-exploration. The Multiplate® platelet analyser is better in this regard than standard thromboelastography (TEG).

On 01/04/2012 the following changes were made to the trial record:
1. The scientific title was changed from 'An observational pilot study assessing the usefulness of measuring platelet function after cardiac surgery' to 'The role of point-of-care assessment of platelet function in predicting postoperative bleeding and transfusion requirements after Coronary Artery Bypass Grafting (CABG)'
2. The study design was changed from 'Prospective controlled observational double-blind trial' to 'Prospective controlled double-blind single-centre trial'
3. The target number of participants was changed from 80 to 84

Ethics approval required
Old ethics approval format

Ethics approval(s)
NREC Committee Black Country, West Midlands, 05/07/2011, ref: 11/WM/0130

Study design
Prospective controlled double-blind single-centre trial

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Coronary Artery Disease / Coronary Artery Bypass Graft / Antiplatelet medications

Interventions
Current interventions as of 01/04/2014:
Group A (n=42) will include patients who were on anti-platelet drugs until the day of surgery.
Group B (n=42) will include patients who stopped anti-platelet drugs at least 5 days pre-operatively.

Patients enrolled for the study will be treated according to institutional routine during the intraoperative and postoperative period. The only additional intervention will be blood sampling immediately after inserting the arterial line and after protamine administration after cessation of cardiopulmonary bypass. Anesthetists and surgeons will be blinded to the results of the Multiplate® measurements.

The TEG measurements will be used as per current practice to influence our decision making in terms of using blood products. Additional protamine or blood products will be given based on our clinical guidelines.

Previous interventions:
Control group of patients (Group A) who did not receive antiplatelet therapy or stopped antiplatelet therapy several days prior to CABG. Study group (Group B) will include patients who continued antiplatelet medications until the day of surgery.

Patients enrolled for the study will be treated according to institutional routine during the intraoperative and postoperative period. The only additional intervention will be blood sampling immediately after inserting the arterial line and after protamine administration after cessation

of cardiopulmonary bypass. Anesthetists and surgeons will be blinded to the results of the Multiplate® measurements. The TEG measurements will be used as per current practice to influence our decision making in terms of using blood products.

Additional protamine or blood products will be given based on our clinical guidelines. Blood loss for the first 8 hours will be recorded. Use of blood products intraoperatively or postoperatively will be also recorded for the first 24 hours.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 01/04/2014:
The primary endpoint was to correlate excessive post-operative bleeding defined as blood loss in excess of 2.5 ml/kg/hr in the immediate 3 hours, with the presence of platelet dysfunction as assessed by Multiplate® and TEG.

Previous primary outcome measures:
The primary endpoint is to correlate excessive postoperative bleeding defined as a blood loss of 2.5 ml/kg/hr in the immediate 3 hours and the total bleeding within the first 8 hours post-surgery, with the presence of platelet dysfunction as measured by the Multiplate®.

Key secondary outcome(s))
Current secondary outcome measures as of 01/04/2014:
1. Transfusion requirements for blood and blood products
2. Overall blood loss within 8 hours of surgery
3. Postoperative complications
4. Intensive care unit (ICU) length of stay
5. Hospital length of stay

Previous secondary outcome measures:
1. Transfusion requirements for blood and blood products
2. Comparison of Multiplate® and TEG
3. Postoperative complications
4. ICU length of stay
5. Hospital length of stay

Completion date
12/06/2013

Eligibility

Key inclusion criteria
1. Male and female patients aged 18 years and over
2. Patient who can give informed consent
3. Patients undergoing first time coronary artery bypass graft (CABG) using cardiopulmonary bypass

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who are unable to consent
2. Patients less than 18 years old
3. Severe liver or renal dysfunction (Altered Liver Function Test, Creatinine >200)
4. Patients who are already part of another study
5. Patient with known bleeding diathesis

Date of first enrolment
16/11/2011

Date of final enrolment
12/06/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Wolverhampton NHS Trust
Wolverhampton
United Kingdom
WV10 0QP

Sponsor information

Organisation
Wolverhampton Coronary Aftercare Support Group (UK)

Funder(s)

Funder type
Charity

Funder Name
Wolverhampton Coronary Aftercare Support Group (UK)

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	01/01/2015		Yes	No