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COagulation and Platelet laboratory Testing in Cardiac surgery

Submission date	Recruitment status	[_] Prospectively registered
21/02/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/07/2018	Circulatory System	

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

Secondary identifying numbers
CS/2009/3228

Study information

Scientific Title
COagulation and Platelet laboratory Testing in Cardiac surgery : a prospective, single-centre observational study

Acronym
COPTIC

Study objectives
To estimate the patient benefit associated with pre and post operative measurement of coagulation factors and platelet function in cardiac surgery patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wiltshire Research Ethics Committee, 09/09/2009

Study design
Prospective single-centre observational study

Primary study design
Observational

Secondary study design
Cohort study

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
Cardiac disease/coronary surgery

Interventions
Participants will undergo standard pre-operative, anaesthetic, surgical and post-operative care according to existing protocols.

1. For the research, two 22.5 ml blood samples will be obtained in the operating theatre at the following time-points:
1.1. Immediately before induction of anaesthesia
1.2. Reversal of heparin anticoagulation

Blood samples will be taken from existing arterial lines that are inserted as part of standard clinical care. No additional venepunctures are required for this study. These samples represent a total additional blood requirement of 45 ml.

Decisions about intra- and post-operative haemostasis and transfusion treatment will be guided by thromboelastography (TEG®) and other laboratory investigations, performed at the discretion of the responsible clinician in accordance with our routine institutional practice. These decisions will not be influenced by participation in this study.

2. Reference coagulation and platelet function assays
2.1. Prothrombin time
2.2. Activated partial thromboplastin time
2.3. Fibrinogen activity (Clauss assay)
2.4. Factor XIII activity (Berichrom assay)
2.5. Heparin activity (anti-Xa assay)
2.6. Endogenous thrombin potential (Thrombin generation assay in platelet poor plasma)
2.7. Von Willebrand factor activity (collagen binding assay)
2.8. D-dimer concentration
2.9. Platelet count
2.10. Immature platelet count
2.11. Mean platelet volume
2.12. Maximum amplitude of platelet aggregation to ADP (Multiplate assay)
2.13. Maximum amplitude of platelet aggregation to AA (Multiplate assay)
2.14. Maximum amplitude of platelet aggregation to TRAP (Multiplate assay)
2.15. Maximum amplitude of platelet aggregation to adrenaline (Multiplate assay)

3. TEG® analysis (post-operative sample only)
Estimates of R-time, K value, MA and LY30 parameters using kaolin and kaolin+ heparinase reagents.

4. Rotational thrombelastography analysis (ROTEM®) (post-operative sample only)
Estimates of R-time, K value and MA parameters using in-tem®, fib-tem®, ap-tem® and hep-tem® reagents

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary predictor and outcome of interest differ by objective. Therefore, they are defined below with respect to each objective separately.
1. Key predictors: results from pre-operative coagulopathy assays
Key outcome: clinical concern about bleeding
2. Key predictor: time between stopping clopidogrel/prasrugrel medication prior to surgery and time of surgery
Key outcomes: results from reference coagulopathy assays
3. Key predictor: time between stopping clopidogrel/prasrugrel medication prior to surgery and time of surgery
Key outcome: clinical concern about bleeding

4. Key predictors: results from post-operative reference coagulopathy assays
Key outcome: category of coagulopathy
5. Key predictors: results from reference coagulopathy assays hypothesised to predict a category of coagulopathy (separate analyses for each category of coagulopathy)
Key outcome: category of coagulopathy (compared to category no coagulopathy)
6. Key predictors: results for parameters from TEG® and ROTEM® point-of-care analysers hypothesised to predict a category of coagulopathy (separate analyses for each category of coagulopathy)
Key outcome: category of coagulopathy (compared to category no coagulopathy)

Secondary outcome measures
No secondary outcome measures

Overall study start date
30/03/2010

Completion date
31/08/2012

Eligibility

Key inclusion criteria
Age >18 years undergoing cardiac surgery at Bristol Heart Institute

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2400

Key exclusion criteria
1. Prisoners
2. Patients unable to give prospective or retrospective consent through mental incapacity

Date of first enrolment
30/03/2010

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Heart Institute
Bristol
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Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research (UK) (ref: RP-PG-0407-10384)

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	25/07/2017		Yes	No