

COagulation and Platelet laboratory Testing in Cardiac surgery

Submission date 21/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/07/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Andrew Mumford

Contact details
Bristol Heart Institute
Level 7, Bristol Royal Infirmary
Bristol
United Kingdom
BS2 8HW
+44 (0)117 342 3152
a.mumford@bristol.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

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)

Key secondary outcome(s)

No secondary outcome measures

Completion date

31/08/2012

Eligibility

Key inclusion criteria

Age >18 years undergoing cardiac surgery at Bristol Heart Institute

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

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

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

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