# COagulation and Platelet laboratory Testing in Cardiac surgery

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

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 heptem® 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)
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 United Kingdom BS2 8HW

### Sponsor information

**Organisation** University Hospitals Bristol NHS Foundation Trust (UK)

#### Sponsor details Research and Development Office University Hospitals Bristol NHS Foundation Trust Education Centre, Level 3 Upper Maudlin Street Bristol England United Kingdom BS2 8AE +44 (0)117 34 20233 mary.perkins@ubht.nhs.uk

**Sponsor type** Hospital/treatment centre

ROR https://ror.org/04nm1cv11

## Funder(s)

**Funder type** Government 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