

# The Effect of Coating of the Cardiopulmonary Bypass Circuit with Poly-2-methoxyethylacrylate (PMEA) on the Systemic Inflammatory Response

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/10/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Moninder Bhabra

### Contact details

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United Kingdom  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0295142271

## Study information

### Scientific Title

Not provided at time of registration.

### Study objectives

To compare outcomes in patients undergoing coronary artery bypass grafting using either standard non-coated cardiopulmonary circuits or circuits in which all components have been coated with PMEA.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Surgery: Cardiopulmonary bypass

### Interventions

Prospective randomised controlled trial

### Intervention Type

Procedure/Surgery

### Phase

Not Specified

### Primary outcome measure

Post-operative blood loss and transfusion requirements, pulmonary, renal, neurological, cardiac and infective complications during hospitalisation, duration of ICU and hospital stay and thirty day mortality. The magnitude of the inflammatory response will be assessed by measuring plasma levels of inflammatory mediators. Platelet function and coagulation will be assessed by flow cytometry and thromboelastography.

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

19/04/2004

### **Completion date**

30/10/2004

## **Eligibility**

### **Key inclusion criteria**

Patients undergoing first-time, isolated, elective coronary artery bypass grafting at UHCW, who have not taken any anti-platelet medication for five days previous to the operation, will be eligible for the study. We aim to recruit 40 patients.

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

40

### **Key exclusion criteria**

1. Patients undergoing repeated surgery
2. Patients undergoing emergency surgery
3. Patients taking antiplatelet medication

### **Date of first enrolment**

19/04/2004

### **Date of final enrolment**

30/10/2004

## **Locations**

### **Countries of recruitment**

England

United Kingdom

**Study participating centre**  
Cardiothoracic Unit, 3rd floor  
Coventry  
United Kingdom  
CV2 2DX

## Sponsor information

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

**Sponsor type**  
Government

**Website**  
<http://www.dh.gov.uk/Home/fs/en>

## Funder(s)

**Funder type**  
Hospital/treatment centre

**Funder Name**  
University Hospitals Coventry and Warwickshire NHS Trust (UK)

**Funder Name**  
NHS R&D Support Funding (UK)

# 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