

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgery: Cardiopulmonary bypass

Interventions

Prospective randomised controlled trial

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Cardiothoracic Unit, 3rd floor

Coventry

United Kingdom

CV2 2DX

Sponsor information**Organisation**

Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration