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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 [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/10/2017	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

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

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
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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