ISRCTN42608249 https://doi.org/10.1186/ISRCTN42608249

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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
18/10/2017

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] 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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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes