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The role of Oxidant Stress on the induction of the Inflammatory Reaction by Cardiopulmonary Bypass

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 11/04/2014	**Condition category** Surgery	

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
N0123138565

Study information

Scientific Title

Study objectives
1. To study the mechanism by which inflammatory response to cardiopulmonary bypass is modulated by oxidant stress
2. To use an ex-vivo model of cardiopulmonary bypass (CPB) and blood samples from patients to investigate oxygen free radicals on the pathogenesis

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Cardiovascular

Interventions
The project is composed of laboratory based investigation and the molecular changes associated with the re-circulation of blood in an artificial surface will be studied using a surrogate model of CPB. A total of 400 patients will be randomised to one of the groups: IHD with and without Hypertension, IHD with and without Hypercholesterolemia, IHD with and without Diabetes, Healthy control.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Proinflammatory cytokines, antioxidant capacity, oxygen free radicals and clinical outcomes.

Secondary outcome measures
Not provided at time of registration

Overall study start date
05/12/2003

Completion date
30/09/2006

Eligibility

Key inclusion criteria
Patients with ischaemic heart disease (IHD) scheduled for elective cardiac operations will be selected.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
05/12/2003

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University Hospitals of Leicester
Leicester
United Kingdom
LE1 4PW

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
University Hospitals of Leicester NHS Trust (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