

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/04/2014	Condition category 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

Dr B Matata

Contact details

University Hospitals of Leicester
c/o Research and Development Office
Leicester General Hospital NHS Trust
Leicester
United Kingdom
LE1 4PW

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