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Biochemical effects of lipopolysaccharide (LPS) adsorber treatment during cardiac surgery using cardio-pulmonary bypass

Submission date 02/04/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/04/2008	**Overall study status** Completed	
Last Edited 25/05/2010	**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

Protocol serial number
PO1192

Study information

Scientific Title

Study objectives
Endotoxin is known to enter the blood stream during cardiac surgery using cardio-pulmonary bypass (CPB), with values peaking during reperfusion. The increase in endotoxin levels is probably caused by gut translocation due to the increased capillary permeability seen during bypass.

Endotoxins are pathogenic triggers for the production of various inflammatory mediators. Raised endotoxin levels therefore increase the risk for postoperative inflammatory complications (sepsis/ Systemic Inflammatory Response Syndrome [SIRS]) and prolonged postoperative recovery.

The Alteco® LPS Adsorber (Alteco Medical AB Lund, Sweden) is an endotoxin adsorption device which has been successfully used in animal studies. It is a CE marked (CE 0088) disposable medical device designed for extracorporeal use. This descriptive study will assess the biochemical effects of Alteco® LPS Adsorber treatment during cardiac surgery using CPB.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 1 Research Ethics Committee, approved on 20/06/2007 (ref: 07/Q0104/49)

Study design
Prospective, randomised, descriptive, single-centre study.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Postoperative inflammatory complications due to raised endotoxin levels.

Interventions
All patients will undergo cardiac surgery using CPB according to clinical routines. In patients randomised to the adsorber treatment, Alteco® LPS Adsorber will be incorporated in the CPB circuit during the whole procedure.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
1. Endotoxin (lipopolysaccharide [LPS])
2. Interleukin-1 (IL1), IL4, IL6, IL8 and IL10
3. Tumor necrosis factor (TNF)-alpha

The above are assessed at the following timepoints:
t0: After anaesthesia before CPB
t60: 60 minutes after the start of CPB
t180: 180 minutes after the start of CPB
t360: 360 minutes after the start of CPB
tPOST: 24 hours after the start of CPB (+/- 1 hour)

Key secondary outcome(s))
1. White blood cells (WBC)
2. Red blood cells (RBC)
3. Haemoglobin (Hb)
4. Hematocrit (HCT)
5. Platelet count,
6. C-reactive protein (CRP)
7. Complement activation
8. Creatinine
9. Blood glucose levels
10. Lactate
11. Thromboelastography (TEG®)
12. Record of mixed venous oxygen saturation (SvO2) during CPB
13. Length of intensive care unit (ICU) stay
14. Adverse events (AEs), recorded untill time point tPOST (with a follow-up made to R&D if continue longer than tPOST)

Timepoints of assessment for outcomes 1-12 above:
t0: After anaesthesia before CPB
t60: 60 minutes after the start of CPB (except CRP, creatinine and TEG®)
t180: 180 minutes after the start of CPB (except CRP, creatinine and TEG®)
t360: 360 minutes after the start of CPB
tPOST: 24 hours after the start of CPB (+/- 1 hour)

Completion date
30/05/2008

Eligibility

Key inclusion criteria
1. Age >18 years, both male and female
2. Patients scheduled for elective complex combined cardiac surgery using CPB
3. Patients scheduled to have cardiac surgery with estimated CPB time in excess of 60 minutes
4. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Planned hypothermia (core temperature <28°C) during surgery
2. Use of steroids in last six months
3. Undergoing immunosuppressive therapy
4. Anaemia (preoperative haemoglobin <10 g/dL)
5. Haematological malignancy
6. Disease of the immune system
7. Female patients of childbearing age
8. Participation in another clinical trial

Date of first enrolment
10/09/2007

Date of final enrolment
30/05/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Anaesthesia
Cambridge
United Kingdom
CB23 3RE

Sponsor information

Organisation
Papworth Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Industry

Funder Name
Alteco Medical AB (Sweden)

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?
Results article	results	01/07/2010		Yes	No