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

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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
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)

## Secondary outcome measures
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)

## Overall study start date
10/09/2007

## 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
16

### 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
England

United Kingdom

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

# Sponsor information

**Organisation**
Papworth Hospital NHS Foundation Trust (UK)

**Sponsor details**
Papworth Everard
Cambridge
England
United Kingdom
CB23 3RE

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.papworthhospital.nhs.uk

**ROR**
https://ror.org/01qbebb31

# Funder(s)

**Funder type**
Industry

**Funder Name**
Alteco Medical AB (Sweden)

# 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/07/2010 | | Yes | No |