

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
Registration date 22/04/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/05/2010	Condition category Surgery	☐ Individual participant data

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)

Primary study design

Interventional

Study design

Prospective, randomised, descriptive, single-centre study.

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 until 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