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A prospective randomised trial to assess the beneficial effect of preoperative hyperoxia therapy on postoperative neuropsychological outcome and inflammatory response after cardiopulmonary bypass

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2010	Circulatory System	

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
N0084118514

Study information

Scientific Title

Study objectives
Does preoperative hyperoxia therapy reduce the serum levels of S100b protein, InterLeukin-6 (IL6), InterLeukin-8 (IL8), L-selectin, P-selectin, Inter-Cellular Adhesion Molecule 1 (ICAM-1), and improve neurological outcome in patients undergoing cardiopulmonary bypass?

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Cardiopulmonary bypass

Interventions
Randomised controlled trial comparing:
1. Hyperoxia therapy
2. No therapy

Study patients will receive the same intra-operative, postoperative and follow-up care as routine patients and as per unit protocol. A 30-day postoperative neuropsychological assessment will be undertaken. The patient will continue to receive routine postoperative follow-up care as per unit protocol.

The patients will undergo three sessions of hyperoxia therapy in the hyperbaric chamber situated at the BUPA Hospital, Anlaby Road, Hull. Each therapy consists of three 20-minute sessions in the hyperbaric chamber breathing 1005 O2 at 2.5 atmospheres interspread with five minutes of air breathing.

Blood samples will be taken for estimation of serum IL6, IL8, sE-selection, ICAM-1 and neutrophil CD18. This will be taken immediate pre-operation, at the end of the operation, 12 hours, 24 hours, 48 hours and fifth day post-operation. Blood samples for estimation of S100B will be taken immediate pre-operation, at the end of the operation, two hours and four hours after the operation.

A baseline neuropsychological test will be done within 24 h prior to the operation. The first postoperative assessment will be carried out when the performance is more stable, that is, three months postoperatively. To ensure objectivity and reliability of the assessment, the testing of each patient will be undertaken by the same doctor.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Data collected will be entered into the research department computer and statistical analysis will be done using the Stars Direct Package. Demographics, measures and results of data analysis will be represented as tables, graphs, bar charts and pie charts where applicable. Statistical significance will be set at P-value < 0.05.

Secondary outcome measures
Not provided at time of registration

Overall study start date
07/10/2002

Completion date
15/01/2004

Eligibility

Key inclusion criteria
A total of 50 patients (25 each group), between 20 and 75 years of age undergoing cardiopulmonary bypass.

Participant type(s)
Patient

Age group
Adult

Sex

Not Specified

Target number of participants
50

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
07/10/2002

Date of final enrolment
15/01/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiothoracic Surgery
Cottingham, East Yorkshire
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Department of Health (UK)

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

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2005		Yes	No