ISRCTN38289094 https://doi.org/10.1186/ISRCTN38289094

Influence of Dextran-70 on Systemic Inflammatory Response and myocardial ischaemia-reperfusion following cardiac operations

Submission date 26/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/01/2007	**Overall study status** Completed	
Last Edited 30/10/2008	**Condition category** 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
N/A

Study information

Scientific Title

Acronym
DISIR

Study objectives
Cardiac surgery on CardioPulmonary Bypass (CPB) results in a complex immune response which is characterised by the activation of all inflammatory pathways and is strongly related to increased postoperative morbidity and mortality.

Animal experiments have confirmed that haemodilution with dextran decreases the endothelial adhesion of neutrophils in the post-ischaemic phase. However there are no exact clinical data in the literature that would support the anti-inflammatory effect of dextran infusion following cardiac surgery. Our hypothesis is that dextran inhibits the inflammatory mediator cascades after cardiac operations and diminishes ischaemia-reperfusion injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval gained from the Local Ethical Committee of Zala County Hospital on the 2nd February 2001.

Study design
Prospective, randomised, double blind trial

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
Myocardial ischaemia-reperfusion injury

Interventions

Two groups were formed following computerised randomisation. Twenty patients were given dextran-70 (6%) infusion (Macrodex, Pharmalink, Inc., Upplands Vasby, Sweden) (group A), whilst in the control group 20 patients were given oxypolygelatin (5.5%) infusion (Gelifundol, Biotest Pharma, Inc., Dreieich, Germany) (group B).

Following the induction of anaesthesia, artificial colloid was administered using infusion pumps (Model 591, IVAC, Inc., San Diego, USA). After the application of hapten inhibition by 20 ml dextran-1 (Promit, Fresenius Kabi, Inc., Norge AS, Norway), dextran-70 infusion was used in the dose of 7.5 ml/kg before CPB, and 12.5 ml/kg for 14 hours following the cessation of CPB. Gelatin was infused by the same body-weight based volume as dextran.

Arterial blood samples were obtained at six time points: before the operation (t0), ten minutes (t1), two hours (t2), four hours (t3), 24 hours (t4) and 44 hours (t5) after the cessation of CPB.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dextran, oxypolygelatin

Primary outcome measure
We have investigated the inflammatory mediator response determing the plasma concentration of some inflammatory mediators (procalcitonin, C-reactive protein, interleukin 6, interleukin 6r, interleukin 8, interleukin 10, macrophage migration inhibitory factor, soluble endothelial leukocyte adhesion molecule-1, soluble intercellular adhesion molecule-1, vascular cell adhesion molecule-1) and those of the ischaemia-reperfusion (cardiac troponin-I) between the dextran treated and the control groups following cardiac surgery.

Secondary outcome measures
Cardiopulmonary bypass alters vasomotor regulation reducing the endothelium dependent relaxation. We have investigated the effect of dextran on the kinetics of the haemodynamic variables (heart rate, arterial blood pressure, cardiac index, stroke volume index, systemic vascular resistance index, intrathoracic blood volume index, extravascular lung water index).

Overall study start date
26/05/2002

Completion date
10/01/2004

Eligibility

Key inclusion criteria
First time cardiac surgery on Cardiopulmonary Bypass (CPB) (Coronary Artery Bypass Graft [CABG] or aortic valve replacement)

Participant type(s)

Patient

Age group
Not Specified

Sex
Both

Target number of participants
40 (following pilot study)

Key exclusion criteria
1. 'Redo' operation
2. Hepatic disease
3. Renal dysfunction
4. Immunological disease
5. Steroid treatment
5. Intake of aspirin or other cyclooxygenase-inhibitor within seven days prior to surgery
6. Known allergy to volume expanders used in the study

None of the patients received volatile anaesthetics, steroids or aprotinin and haemofiltration were not used either. No shed mediastinal blood was retransfused during the post-operative period.

Date of first enrolment
26/05/2002

Date of final enrolment
10/01/2004

Locations

Countries of recruitment
Hungary

Study participating centre
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Sponsor information

Organisation
European Society of Anesthesiologists (ESA) (Belgium)

Sponsor details
24 Rue des Comediens
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Sponsor type
Research organisation

Website
http://www.euroanesthesia.org/

ROR
https://ror.org/0102p7z54

Funder(s)

Funder type
Research organisation

Funder Name
European Society of Anesthesiologists (ESA) (Belgium) - Clinical Research Grant award

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	01/05/2007		Yes	No