

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

<b>Submission date</b> 26/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/10/2008	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Karoly Gombocz

### Contact details

Hajnal u. 19.  
Zalaegerszeg  
Hungary  
8991  
gombocz@freemail.hu

## 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 determining 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**

Hajnal u. 19.

Zalaegerszeg

Hungary

8991

## Sponsor information

**Organisation**

European Society of Anesthesiologists (ESA) (Belgium)

**Sponsor details**

24 Rue des Comediens  
Brussels  
Belgium  
B-1000

**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?
<a href="#">Results article</a>	results	01/05/2007		Yes	No