

# 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
<b>Registration date</b> 03/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/10/2008	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

## 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.

## **Primary study design**

Interventional

## **Study design**

Prospective, randomised, double blind trial

## **Study type(s)**

Treatment

## **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(s)**

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.

**Key secondary outcome(s)**

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).

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

All

**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)

**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

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

## Study outputs

Output type

[Results article](#)

Details  
results

Date created

01/05/2007

Date added

Peer reviewed?

Yes

Patient-facing?

No