

# Autologous bone marrow-derived cells for cardioprotection during heart surgery

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 14/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/07/2021	<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

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2006-006480-23

**Protocol serial number**  
UHL Ref: 10,176

# Study information

## Scientific Title

Autologous bone marrow-derived cells for cardioprotection during heart surgery

## Study objectives

The principal hypothesis that will be tested is that the administration of autologous Bone Marrow Cells (BMCs) during cardiac surgery can reduce myocardial ischaemic injury and improve cardiac function and clinical outcome. This small clinical trial aims to prove the laboratory concept that autologous BMCs protect the heart against myocardial injury caused by ischaemia and serve as a base for a large trial aimed at investigating whether BMCs improve the clinical outcomes and have an impact on the costing of care.

The specific objectives of this project are:

1. To investigate in a randomised, double-blinded study whether the administration of autologous bone marrow cells as an additive to cardioplegia reduces myocardial ischaemic injury during cardiac surgery.
2. To study whether the administration of autologous BMCs improves cardiac function during the early period following cardiac surgery.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Under review at present.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Ischaemic heart disease

## Interventions

Patients with triple vessel coronary artery disease with or without associated significant disease of the left main stem and undergoing elective CABG surgery will be recruited for the study.

Patients will be randomised at the time of surgery to either of the following study groups:

1. Group I: control - receiving serum alone
2. Group II: receiving BMCs at then end of the first dose of cardioplegia and then at the end of each new dose of cardioplegia

Autologous BMCs (diluted in 10 mL of autologous serum) will be administered into the aortic root at the end of cardioplegia infusion (last 20 mL of cardioplegia to ascertain that BMCs remain within the coronary vasculature during the ensuing ischaemic period) or the equivalent

amount of serum to act as control. Blood cardioplegia will be used with an initial dose of 1 L and 0.5 L following the completion of each coronary anastomosis, usually every 15 - 20 minutes. Blood samples will be taken before surgery and four, 12, 24 and 48 hours after surgery for determination of plasma levels of troponin I. An Electrocardiogram (ECG) will be recorded before surgery and at four and 24 hours for the identification of new electrical ischaemic changes. A Swan-Ganz catheter will be floated into the pulmonary artery during the induction of anaesthesia for the assessment of cardiac function (cardiac index and stroke volume index) before surgery and 30 minutes, one, two, four, eight, 12, and 24 hours after surgery.

Cardiac filling pressures (central venous pressure between 8 and 12 mmHg and pulmonary capillary wedge pressure between 12 and 16 mmHg with appropriate transfusion), heart rate (between 70 and 90 beats/minute with atrioventricular pacing if required) and systemic vascular resistance index (between 1200 and 1800 units using vasodilators such as Glyceryl Trinitrate [GTN] and vasoconstrictors as vasopressin if required) will be kept within the physiological range. Hospital mortality, the need for inotropic drugs (dopamine more than 10 mg/Kg/min and any other inotropic drug) or intra-aortic balloon pump to support cardiac function and the presence of severe cardiac arrhythmias requiring cardioversion or the use of anti-arrhythmic drugs will be recorded.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

Troponin I in plasma

### **Key secondary outcome(s)**

1. Left ventricular function
2. Composite clinical outcome

### **Completion date**

03/07/2007

## **Eligibility**

### **Key inclusion criteria**

1. Triple vessel coronary artery disease with or without significant disease of the left main stem with indication of elective surgical revascularisation
2. Left ventricular ejection fraction greater than 40%
3. Age 20 to 80 years

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Sex**

Not Specified

**Total final enrolment**

44

**Key exclusion criteria**

In addition to not being compliant to the inclusion criteria, the following criteria will be sufficient to exclude patients from entering the study:

1. Cardiogenic shock (need for inotropic drugs, intra-aortic balloon pump)
2. Previous Coronary Artery Bypass Graft (CABG)
3. Percutaneous Coronary Infusion (PCI) in the previous three months
4. History of neoplastic disease
5. History of bleeding disorder
6. Chronic inflammatory disease
7. Active infection
8. Renal impairment (creatinine more than 180 mmol/l)
9. Liver dysfunction (Glutamate Oxalate Transferase [GOT] more than 2 x Upper Limit of Normal [ULN] or International Normalised Ratio [INR] more than 1.5 x ULN)
10. Diabetes
11. Chronic treatment with oral antibiotic agents

**Date of first enrolment**

03/01/2007

**Date of final enrolment**

03/07/2007

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Cardiac Surgery Group**

Leicester

United Kingdom

LE3 9QP

**Sponsor information**

**Organisation**

University Hospitals of Leicester NHS Trust (UK)

ROR

<https://ror.org/02fha3693>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Cardiac Surgery Group (UK) - a specific group within the University of Leicester and Glenfield Hospital

## 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?
<a href="#">Results article</a>		26/06/2009	19/07/2021	Yes	No
<a href="#">Abstract results</a>		01/02/2004		No	No
<a href="#">Abstract results</a>		01/11/2006		No	No