ISRCTN22639386 https://doi.org/10.1186/ISRCTN22639386

Autologous bone marrow-derived cells for cardioprotection during heart surgery

Submission date	Recruitment status	[_] Prospectively registered
01/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/07/2021	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
2006-006480-23

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
Troponin I in plasma

Secondary outcome measures
1. Left ventricular function
2. Composite clinical outcome

Overall study start date
03/01/2007

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

Age group
Adult

Sex
Not Specified

Target number of participants
44 (22 in bone marrow group, 22 in control group)

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
England

United Kingdom

Study participating centre
Cardiac Surgery Group
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

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Trust Headquarters
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Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/about-us/contact-us/uhl-hq

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

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?
Abstract results		01/02/2004		No	No
Abstract results		01/11/2006		No	No
Results article		26/06/2009	19/07/2021	Yes	No