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Metabolic substrate support in left ventricular hypertrophy -HINGE Trial (Hypertrophy, Insulin, Glucose and Electrolytes Trial)

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 28/03/2012	**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

Protocol serial number
N0265150472

Study information

Scientific Title

Study objectives

This study assesses the effect of supplementing naturally-occurring insulin and energy sources (glucose) on heart protection during aortic valve replacement surgery. These treatments have a sound experimental basis for improving outcome. If this improvement is confirmed surgical results could be materially improved. We will be studying heart function, heart muscle energy stores and chemicals which quantify the amount of heart muscle injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Aortic valve replacement

Interventions
On the morning of surgery patients will be randomised to one of two groups. There are 2 groups of patients in this trial, allocated to receive placebo or G.I.K.
1. Group A. receive dextrose 5% run at 0. 75ml/kg/h rounded to the nearest 10 mls/hr starting at sternotomy and finishing 6 hours following release of the aortic cross clamp.
2. Group B: a central intravenous G.I.K. (500 ml of 40% glucose 35 units insulin 50 mmols of KC1) run at 0. 75 mis/kg/hr rounded to the nearest 10 mls/hr starting at sternotomy and finishing 6 hours following release of the aortic cross clamp.

Blood for baseline CKMB and cTnI will be drawn for centrifuge and storage and arterial blood gases (ABC) will be withdrawn for immediate analysis in the anaesthetic room before standard induction using the arterial line routinely inserted before induction of anaesthesia additional) . Alter induction a pulmonary artery balloon flotation catheter will be positioned in the anaesthetic room and the patient then transferred to the operating room (normal clinical practice or additional). Approximately 40% have such catheters placed routinely for clinical reasons - in the study they will be used in every patient).

Baseline cardiac output studies, pulmonary capillary wedge pressures (normal clinical practice in the patients or additional).

Surgery will proceed as normal with 1/2 hourly K+ and blood glucose sampling pre-CPB, 20 minutely during CPB and 1 hourly post CPB with protocol based management of blood glucose and potassium. The protocol is based on that used in the DIGAMI study (additional).

Anaesthetic and CPB management will be standardized to control for known factors affecting outcome including pH management, C02 control, re-warming protocols etc. Myocardial protection will be afforded by cold blood cardioplegia. Criteria for the initiation of inotropic or

other support will be standardized. Ventilator weaning criteria are standard (normal clinical practice).

During the conduct of the operation in certain cases, the surgeon will place a monitoring cannula in the coronary sinus under direct vision. Such placement is a standard technique for administration of retrograde cardioplegia. In this study it will be placed to undertake oximetric measurement and will be removed at the end of cardiopulmonary bypass. Its insertion and removal are performed under direct vision. The risk associated with this procedure is minimal and should be no greater than the risk of pulmonary flotation catheter insertion (i.e.1:15000 adverse events) (additional).

Myocardial biopsies for will be performed just prior to aortic cross clamp application, just prior to aortic cross clamp release and after 10 minutes of reperfusion. Myocardial diopsies will be snap frozen and stored as mentioned above (additional). In addition a small amount of epicardial and thigh fat and rectus abdominis muscle (pea size) will be removed at approximately the same time. These will be taken from exposed sites through the sternotomy and long saphenous vein harvest sites (additional).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
13/08/2008

Eligibility

Key inclusion criteria
Patients eligible for entry into the trial will be consulted and recruited in:
1. Pre-surgical consultation clinic
2. Pre-admission clinic
3. During hospital admission for surgery

Before surgery they will have an echocardiogram/MRI scan to assess left ventricular hypertrophy. 2D directed M-mode echocardiography will be used to determine LV mass using the anatomically-validated cube formula. Consistency will be cross-checked using LV mass quantification from the area-length 2D method. There is no risk associated with transthoracic echocardiography. A subset of subjects will also undergo LV mass assessment using MRS. LV mass will be calculated using serial contiguous short axis TrueFISP cine sequences with 7mm slice thickness and 3mm gap using a 1. 5-Tesla magnet. Analysis will be performed off-line using Siemens ARGOS software. There is no biological risk to MR scanning, although patients with ferromagnetic material within the body have to be excluded (the most common example is that of older cerebral aneurysm clips).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients with ferromagnetic material within the body.

Date of first enrolment
13/08/2004

Date of final enrolment
13/08/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cardiac Surgery
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Sponsor information

Organisation
Department of Health

Funder(s)

Funder type

Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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?
Results article	results	18/01/2011		Yes	No