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Effect of ischaemic pre-conditioning on cardiac function during elective open abdominal aortic aneurysm repair

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 15/02/2013	**Condition category** Surgery	

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544174260

Study information

Scientific Title

Study objectives
To measure the effect of a non-invasive technique called ischaemic preconditioning (IPC) on cardiac function during surgery to repair aortic aneurysms (an abnormal dilatation of the major artery in the body).

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Open abdominal aortic aneurysm repair

Interventions
The technique of IPC temporarily reduces the blood flow to the patients legs in sequence for five minutes at a time. This causes the muscle in the patients legs to release various chemicals that can protect tissue against damage due to periods of reduced blood and oxygen supply. Once blood flow to the leg is fully restored, these substances enter the general circulation and can protect distant organs such as the heart, brain or kidneys from damage due to reduced blood flow. The Vascular Research Unit at Addenbrookes Hospital has shown that IPC reduces the levels of a protein in the blood called troponin I which is a marker of heart muscle damage.

We would like to investigate the effect of IPC on heart function by using established perioperative cardiovascular monitoring techniques.

IPC is not standard practice in major vascular surgery at present.

The Vascular Research Unit is undertaking a randomised controlled trial to look at the effect of IPC on renal function during AAA repair. We would like to use the monitoring techniques outlined below in the patients assigned to IPC in the randomised controlled trial to collect prospective data on how IPC effects heart function.

The patients assigned to the IPC group will have the blood flow to their legs reduced for two five minute periods by clamping the main artery to each leg in turn during the early stages of their operation. Cardiac output and allied haemodynamic data will be measured with a LiDCO monitor. This is a minimally invasive, continuous method of measuring cardiac output and deriving cardiac index, systemic vascular resistance and stroke volume variance. These are routine measures of cardiac function. This monitor uses clinically insignificant doses of intravenous lithium that are non toxic and do not harm or affect the patient in any way. The monitor is used routinely on patients in the Intensive Care Unit and HDU in Addenbrooke's hospital. The LiDCO is attached to an arterial drip. A central venous drip is also required as a port of injection for the lithium. Both of these drips are sited as routine monitors during such surgery and maintained in the post operative period. A 12 lead ECG monitor will be used to measure any cardiac ischaemia and serum troponin I levels to measure any cardiac injury.

No adverse events have been reported during IPC in previous trials by the Vascular Research Unit. The additional monitoring will not be in any way harmful to the patient and is routinely employed in many UK hospitals. Patients will be given an information sheet about the study when they attend outpatients about eight weeks before surgery. Contact details will be provided should they wish to discuss the study further. There will be opportunity to discuss any issues at the pre-admission clinic. All these patients are admitted the day before surgery. They will then be asked if they wish to participate in the study. Written informed consent will be obtained.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Cardiac output measurement.

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/03/2006

Completion date
31/03/2009

Eligibility

Key inclusion criteria

Any patient scheduled to undergo elective infra-renal aneurysm repair will be eligible for inclusion. The following entry criteria with respect to renal function shall apply:
1. No history of acute renal failure
2. No history of renal replacement therapy (haemodialysis, haemofiltration, peritoneal dialysis)
3. No previous renal transplant
4. No previous renal disease
5. Serum creatinine less than 150 micromols/L at pre-operative assessment
6. Serum urea less than 20 mmols/L at pre operative assessment

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
40 - 9 patients as of July 2008

Key exclusion criteria
1. Patients with aneurysms above the level of the renal arteries have a very high risk of renal damage during surgery. These aneurysms are relatively uncommon. Their inclusion could bias the trial.
2. Patients with lower limb amputations will be excluded as they have less muscle in their lower limbs. Thus, the IPC stimulus could be inadequate and bias the trial results.
3. Patients with ankle-brachial pressure index < 0.7 will be excluded as the IPC technique could trigger acute lower limb ischaemia.
4. Patients who have undergone previous endovascular repair of the aneurysm will be excluded.

Date of first enrolment
31/03/2006

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Box 17
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK) - Own Account

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	p.4	01/01/2009		No	No