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Metabolic Substrate Support and Tight Glycaemic control in Abdominal Aortic Aneurysm (AAA) Repair

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/08/2015	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

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
N0265126499

Study information

Scientific Title
Metabolic Substrate Support and Tight Glycaemic control in Abdominal Aortic Aneurysm (AAA) Repair

Study objectives
It is hypothesised that glucose-insulin-potassium (GIK) solution will reduce the incidence of perioperative myocardial ischaemia and attenuate the inflammatory response associated with AAA repair. It is further hypothesised that there will be a proportion of patients undergoing abdominal non vascular surgery in which there is cardiac and skeletal muscle damage and systemic inflammation detected. This proportion is however hypothesised to be less than in AAA repair.

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)
Hospital

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: Abdominal aortic aneurysm (AAA) repair

Interventions
Patients are randomised to receive either glucose-insulin-potassium or ALK or normal saline solution.
Specimen collection in Theatre. Selly Oak Hospital Intensive Therapy Unit (ITU) and on Selly Oak Hospital Vascular Ward. Blood (10 ml) and urine (5 ml from catheter bag) samples will be collected pre-operatively, during the procedure and at intervals up to 3 days postoperatively. In total, 5 sets of blood and 8 sets of urine specimens will be collected per patient. Blood will be collected from an arterial line or central line and will rarely involve additional venepuncture.

Cardiac and inflammatory markers measured on these samples will include cardiac Troponin I, total Creatine Kinase (CK), CK myocardial band (CK-MB) fraction, C-reactive protein (CRP), interleukin 6 (IL6) and urinary microalbumin.
In addition, hourly monitoring of arterial blood gases, glucose, lactate and potassium will be taken from commencement of study solution until 6 hours following completion of study solution infusion. This will involve 15 x ml blood samples taken painlessly from an arterial line and ensures the safety of the study.

Femoral Venous Blood Sampling in Theatre and Selly Oak Hospital ITU
Blood (5 ml) will be collected before surgery, during surgery and up to 24 hours following surgery. In total 5 sets of specimens will be collected per patient. This is a technique of blood taking that is widely employed by medical staff in hospitals when patients have poor arm veins for phlebotomy. Risks of the procedure are as for normal blood taking, i.e. a bruise.

Gastric tonometry
After induction of anaesthesia, a gastric tonometer will be inserted by the surgical research fellow to monitor the splanchnic perfusion. This is an adapted nasogastric tube which has gastric pH monitoring capabilities. A nasogastric tube is normally placed in all patients undergoing AAA repair.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Glucose-insulin-potassium

Primary outcome measure
A reduction in cardiac Tropinin I release of 0.75 standard deviations from the mean in the GIK group compared with the control group.

Secondary outcome measures
Secondary (in GIK group) - Reduced cardiac ischaemia as measured by electrocardiogram (ECG), creatinine kinase (CK) total and CK-MB, reduced inflammatory response as measured by IL6, CRP, gastric tonometry - reduced Intensive Therapy Unit (ITU) stay, intubation time.

Overall study start date
05/09/2003

Completion date
05/09/2008

Eligibility

Key inclusion criteria
60 patients requiring elective infra-renal aortic surgery for aneurysm disease will be recruited over 18 months in the Department of Vascular Surgery. All 60 patients will be randomised to receive the "study solution" either ALK or normal saline control.

A further group of 30 patients (age and sex matched controls) undergoing elective abdominal, non vascular surgery will also be studied. They will not have any therapeutic interventions but will be managed as per usual by the medical teams looking after them. Cardiac and skeletal muscle damage and systemic inflammation will be measured in these patients for up to 5 days post operatively.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Pregnancy
2. Patients <18 years old
3. Patients with Diabetes Mellitus
4. Patients who have not given informed consent
5. Patients who are unable to give informed consent
6. Patients with a preoperative haemoglobin of <11 g/dl
7. Patients undergoing emergency surgery for ruptured abdominal aortic aneurysm
8. Patients with a history of sensitivity reaction to the solutions under study
9. Patients participating in another study
10. Patients with renal impairment. creatinine >200 gmol/I

Date of first enrolment
05/09/2003

Date of final enrolment
05/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Selly Oak Hospital
Birmingham

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Sponsor information

Organisation
Department of Health

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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

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