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Remote ischaemic preconditioning to protect the myocardium during abdominal aortic aneurysm repair

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 16/07/2009	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544122070

Study information

Scientific Title

Study objectives
Patients undergoing major vascular surgery are at significant risk of developing postoperative myocardial complications, particularly myocardial infarction. Protecting the heart during the perioperative period could provide a method to reduce morbidity and mortality after vascular surgery. Ischaemic preconditioning is a well recognised phenomenon, whereby a brief period of ischaemia followed by reperfusion prior to a prolonged ischaemic event can provide protection from cellular injury. Protection can be performed either by a stimulus to the myocardium itself or by ischaemia at a site distant to the heart. The aim of this study is to determine whether remote ischaemic preconditioning confers a reduction in myocardial damage in patients undergoing abdominal aortic aneurysm 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

Health condition(s) or problem(s) studied
Aortic aneurysm repair

Interventions
Randomised controlled trial:
1. Abdominal aortic aneurysm repair alone
2. Abdominal aortic aneurysm repair with intermittent cross clamping/perfusion of common iliac artery
Postoperatively, patients will have cardiac troponin and creatine kinase MB (CKMB) recorded on days 1, 3 and 7. Holter monitoring is to be continued until 48 h post operation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
A reduction in myocardial damage as assessed by serum measurement of cardiac troponin and Holter electrocardiogram.

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/01/2003

Completion date
09/01/2006

Eligibility

Key inclusion criteria
72 Subjects aged 18-90.

Participant type(s)
Patient

Age group
Other

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
72

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
10/01/2003

Date of final enrolment
09/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Vascular Surgery
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Research council

Funder Name
Cambridge Consortium - Addenbrookes (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/09/2007		Yes	No