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Does ischaemic preconditioning reduce adverse events following endovascular repair of abdominal aortic aneurysms? A randomised controlled pilot trial

Submission date
06/06/2006

Recruitment status
No longer recruiting

Registration date
17/08/2006

Overall study status
Completed

Last Edited
17/08/2010

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Michael Gaunt

Contact details
Cambridge Vascular Unit
Box 201, Level 7
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 2QQ
+44 (0) 1223 217246
michael.gaunt@addenbrookes.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Remote ischaemic preconditioning will reduce subclinical renal and myocardial damage following endovascular abdominal aortic aneurysm repair.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Cambridge Research Ethics Committee on 20th June 2006 (ref: 06/Q0108/127).

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
Abdominal aortic aneurysm

Interventions
Intervention:
Remote ischaemic preconditioning. After induction of anaesthesia, an inflatable cuff will be used to render each leg ischaemic for ten minutes. The operation will then proceed in the usual fashion.

Control:
The control group will receive usual care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Urinary retinol binding protein levels pre- and post-operatively.

Secondary outcome measures
1. Urinary albumin-creatinine ratios
2. Urinary Tumour Necrosis Factor (TNF), Tumour Necrosis Factor Receptor (TNFR) 1 and TNFR2
3. Serum TNF, TNFR1 and TNFR2
4. Serum creatinine
5. Creatinine clearance
6. Glomerular filtration rate
7. Cardiac index as measured by the LiDCO system
8. Peripheral vascular resistance as measured by the LiDCO system
9. Ischaemia detected on 12-lead electrocardiogram

Overall study start date
15/06/2006

Completion date
14/06/2007

Eligibility

Key inclusion criteria
Any patient undergoing elective endovascular repair of an abdominal aortic aneurysm.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Ankle-brachial pressure index less than 0.7
2. Previous renal transplant
3. Previous renal disease
4. Previous renal replacement therapy
5. Previous endovascular aneurysm repair
6. Baseline serum creatinine more than 150 mmols/l

7. Baseline serum urea more than 20 mmols/l
8. Previous lower limb amputation

Date of first enrolment
15/06/2006

Date of final enrolment
14/06/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge Vascular Unit
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
c/o Dr John Bradley
Director of Research and Development
Research and Development Office
Box 146
Addenbrooke's Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 2QQ
+44 (0) 1223 274486
john.bradley@addenbrookes.nhs.uk

Sponsor type
Hospital/treatment centre

Website

http://www.addenbrookes.nhs.uk/research

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Research organisation

Funder Name
Cambridge Vascular Unit Research Fund (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	01/12/2009		Yes	No
Results article	results	01/07/2010		Yes	No