

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	<input type="checkbox"/> Prospectively registered
Registration date 17/08/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/08/2010	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Urinary retinol binding protein levels pre- and post-operatively.

Key secondary outcome(s)

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

Completion date

14/06/2007

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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

United Kingdom

England

Study participating centre

Cambridge Vascular Unit
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Research organisation

Funder Name

Cambridge Vascular Unit Research Fund (UK)

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	01/12/2009		Yes	No
Results article	results	01/07/2010		Yes	No