

Does ischaemic pre-conditioning reduce renal damage during elective infra-renal aortic aneurysm repair? Randomised controlled trial.

Submission date 02/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/12/2010	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

Protocol serial number
05/Q0108/276 - NRR ref N0544174223

Study information

Scientific Title

Study objectives

Ischaemic preconditioning during open infra-renal aortic aneurysm repair will reduce intra-operative renal damage.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The trial has been reviewed and approved by the Cambridgeshire Research Ethics Committee, October 2005. REC reference number 05/Q0108/276.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Abdominal aortic aneurysm

Interventions

Participants will be randomised to undergo clamping or not. The intervention consists of application of a crossclamp to each common iliac artery for 10 minutes followed by 10 minutes reperfusion time during the dissection phase of the operation. Each common iliac artery will be clamped in sequence not simultaneously. The temporary interruption to blood flow in the leg provides an ischaemic stimulus that appears to protect the heart from damage during the operation. This trial aims to determine if the same technique protects the kidneys.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Post-operative urinary albumin-creatinine ratios
2. Post-operative creatinine clearance
3. Post-operative glomerular filtration rate

Key secondary outcome(s)

No secondary outcome measures

Completion date

14/11/2006

Eligibility

Key inclusion criteria

Patients undergoing elective open repair of an infra-renal abdominal aortic aneurysm.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pre-existing renal failure
2. Baseline serum creatinine >150 µmols/l
3. Baseline serum urea >20 mmols/l
4. Previous history of acute renal failure
5. Previous renal transplant
6. Previous renal disease
7. Previous endovascular aneurysm repair
8. Previous renal replacement therapy
9. Suprarenal aneurysm
10. Ankle-brachial pressure index <0.7

Date of first enrolment

14/11/2005

Date of final enrolment

14/11/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Consultant Vascular Surgeon

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Cambridge Vascular Unit's own in-house research fund. This is not a trust own account or an NHS R&D funded project.

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	01/07/2010		Yes	No