ISRCTN89918035 https://doi.org/10.1186/ISRCTN89918035

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

Registration date
15/11/2005

Overall study status
Completed

Last Edited
16/12/2010

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
Consultant Vascular Surgeon
Cambridge Vascular Unit
Box 201 Level 7
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 216992
michael.gaunt@addenbrookes.nhs.uk

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