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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/11/2005	**Overall study status** Completed	
Last Edited 16/12/2010	**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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
14/11/2005

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

Age group
Adult

Sex
Both

Target number of participants
40

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
England

United Kingdom

Study participating centre
Consultant Vascular Surgeon
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

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

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

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	01/07/2010		Yes	No