

The effect of the arm blood pressure cuff inflations during abdominal aortic aneurysm surgery as a measure of protecting kidney and heart from injury

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| Submission date 23/03/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 07/06/2010 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 29/01/2019 | Condition category Surgery | <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
SVH/AAA/ TR1

Study information

Scientific Title

The effect of the arm blood pressure cuff inflations during open abdominal aortic aneurysm surgery as a measure of protecting kidney and heart from injury: a double-blinded, randomised controlled trial

Study objectives

Remote ischaemic preconditioning using upper arm blood pressure cuff will significantly reduce renal and myocardial injury following open Abdominal Aortic Anuerysm (AAA) repair.

As of 23/11/2010 this record has been updated to include an amended anticipated end date; the initial end date at the time of registration was 30/06/2011.

Please note that as of 18/12/2012, the anticipated end date has been updated from 30/06/2012 to 31/03/2013.

Further reading

1. <http://www.ncbi.nlm.nih.gov/pubmed/15337028>

Halkos ME, Kerendi F, Corvera JS, Wang NP, Kin H, Payne CS, Sun HY, Guyton RA, Vinten-Johansen J, Zhao ZQ. Myocardial protection with postconditioning is not enhanced by ischemic preconditioning. *Ann Thorac Surg.* 2004;78:961-969.

2. <http://www.ncbi.nlm.nih.gov/pubmed/15793629>

Vinten-Johansen J, Zhao ZQ, Zatta AJ, Kin H, Halkos ME, Kerendi F. Postconditioning: a new link in nature's armor against myocardial ischemia-reperfusion injury. *Basic Res Cardiol.* 2005;100:295-310.

3. <http://www.ncbi.nlm.nih.gov/pubmed/18649981>

Wagener G, Gubitosa G, Wang S, Borregaard N, Kim M, Lee HT. Urinary neutrophil gelatinase-associated lipocalin and acute kidney injury after cardiac surgery. *Am J Kidney Dis.* 2008;52:425-433

4. <http://www.ncbi.nlm.nih.gov/pubmed/14506302>

Yellon DM, Downey JM. Preconditioning the myocardium: from cellular physiology to clinical cardiology. *Physiol Rev.* 2003;83:1113-1151.

5. <http://www.ncbi.nlm.nih.gov/pubmed/16258568>

Yellon DM, Hausenloy DJ. Realizing the clinical potential of ischemic preconditioning and postconditioning. *Nat Clin Pract Cardiovasc Med.* 2005;2:568-575.

6. <http://www.ncbi.nlm.nih.gov/pubmed/12860564>

Zhao ZQ, Corvera JS, Halkos ME, Kerendi F, Wang NP, Guyton RA, Vinten-Johansen J. Inhibition of myocardial injury by ischemic postconditioning during reperfusion: comparison with ischemic preconditioning. *Am J Physiol Heart Circ Physiol.* 2003;285:H579-H588.

Ethics approval required

Old ethics approval format

Ethics approval(s)

St. Vincents Healthcare Group Ethics and Medical Research Committee approved on the 9th March 2009

Study design

Single centre two arm double blind randomised controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Abdominal aortic aneurysm surgery

Interventions

Three cycles of upper arm blood pressure cuff inflations 20 mmHg above the baseline, sustained inflation for 5 minutes, deflation for 5 minutes

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Markers of renal injury

1. Urine Neutrophil Gelatinase Associated Lipocalin (NGAL)
2. Creatinine clearance
3. Serum creatinine levels

Outcomes will be measured for three days following surgery

Key secondary outcome(s)

Markers of cardiac injury:

1. Cardiac troponin
2. Electrocardiography (ECG) changes

Outcomes will be measured for three days following surgery

Completion date

31/03/2013

Eligibility**Key inclusion criteria**

1. All patients scheduled for elective or urgent abdominal aneurysm repair
2. Leaking abdominal aneurysm can be taken as long as it is haemodynamically stable

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. AAA rupture, unstable haemodynamics
2. Kidney Disease - Risk Injury Failure Loss End-Stage Kidney Disease (RIFLE) class failure, needing Renal Replacement Therapy (RRT)
3. Upper limb vascular insufficiency
4. Recent Myocardial infarction, less than two weeks

Date of first enrolment

01/07/2009

Date of final enrolment

31/03/2013

Locations

Countries of recruitment

Ireland

Study participating centre

206 Whitecliff

Dublin
Ireland
D16

Sponsor information

Organisation

St Vincent's University Hospital (Ireland)

ROR

<https://ror.org/029tkqm80>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St Vincent's University Hospital (Ireland) - Department of Anaesthesia

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 | 01/10/2014 | 29/01/2019 | Yes | No |