ISRCTN11019960 https://doi.org/10.1186/ISRCTN11019960

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

Submission date 23/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/06/2010	**Overall study status** Completed	
Last Edited 29/01/2019	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ajith Vijayan

Contact details
206 Whitecliff
Rathfarnham
Dublin
Ireland
D16

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
Markers of cardiac injury:
1. Cardiac troponin
2. Electrocardiography (ECG) changes
Outcomes will be measured for three days following surgery

Overall study start date
01/07/2009

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

Age group
Other

Sex
Both

Target number of participants
60

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)

Sponsor details
Department of Anaesthesia
Elm Park
Dublin
Ireland
D4

Sponsor type
Hospital/treatment centre

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

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