Randomised study of neurocognitive outcome and cerebral embolic events in patients undergoing off-pump and on-pump coronary artery bypass graft surgery

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/09/2004		☐ Protocol		
Registration date 22/10/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 27/11/2015	Condition category Nervous System Diseases	Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Randomised study of neurocognitive outcome and cerebral embolic events in patients undergoing off-pump and on-pump coronary artery bypass graft surgery

Study objectives

- 1. Cerebral injury, determined by neuropsychological testing, is reduced in off-pump compared with on-pump patients
- 2. Perioperative embolisation is reduced in off-pump, compared with on-pump, surgery
- 3. Any reduction in cerebral injury is mediated by a reduction in perioperative embolisation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Wandsworth Local Research Ethics Committee (ref: 01.78.6, R+D Number 00.2431), in October 2001.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Neurocognitive dysfunction

Interventions

Patients are divided into two groups: those undergoing on-pump and those having off-pump coronary artery surgery. Comparisons between intraoperative cerebral embolic burden and postoperative neurocognitive function are made between the two groups.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Post-operative composite neurocognitive score at six months and three years.

Key secondary outcome(s))

The neurocognitive score at discharge and at six weeks, and the total intra-operative microemboli count.

Completion date

01/03/2004

Eligibility

Key inclusion criteria

Patients undergoing first time elective coronary artery bypass surgery.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Αll

Key exclusion criteria

- 1. Previous cerebrovascular accident or Transient Ischaemic Attack (TIA)
- 2. Right or left internal carotid artery stenosis more than or equal to 50%
- 3. Previous cardiac surgery
- 4. Concomitant surgery, e.g. valve replacement
- 5. Previous psychiatric illness, e.g. depression, schizophrenia
- 6. Dialysis-dependent renal failure
- 7. Q-wave myocardial infarction in the past six weeks
- 8. Very poor left ventricular function (ejection fraction less than 20%)
- 9. Illiteracy or non-fluency in English
- 10. Absence of an acoustic window for transcranial Doppler ultrasound monitoring

Date of first enrolment

01/08/2002

Date of final enrolment

01/03/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre St George's Hospital

Department of Cardiac Surgery Blackshaw Road London United Kingdom SW17 0QT

Sponsor information

Organisation

St George's Hospital (UK)

ROR

https://ror.org/0001ke483

Funder(s)

Funder type

Research organisation

Funder Name

St George's Hospital Cardiothoracic Research Fund

Funder Name

The Royal College of Surgeons of England

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	01/03/2004		Yes	No
Results article	results	01/08/2006		Yes	No