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

Submission date
19/09/2004

Recruitment status
No longer recruiting

Registration date
22/10/2004

Overall study status
Completed

Last Edited
27/11/2015

Condition category
Nervous System Diseases

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/08/2002

Completion date
01/03/2004

Eligibility

Key inclusion criteria
Patients undergoing first time elective coronary artery bypass surgery.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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)

Sponsor details
Blackshaw Road
London
United Kingdom
SW17 0QT

Sponsor type
Not defined

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

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