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Long-term cognitive decline after coronary artery bypass grafting: is off-pump surgery beneficial?

Submission date 24/04/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/09/2005	**Overall study status** Completed	
Last Edited 27/09/2017	**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

N/A

Study information

Scientific Title
Long-term cognitive decline after coronary artery bypass grafting: is off-pump surgery beneficial?

Acronym
Octopus Study

Study objectives
The aim of the present study is to compare the effect of coronary bypass surgery with and without cardiopulmonary bypass on cognitive outcome, five years after surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
Random allocation to on-pump or off-pump coronary artery bypass grafting

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary endpoint of the present study is cognitive outcome at five years after surgery. Patients will undergo a battery of ten neuropsychologic tests five years after operation. The tests will be administered by a trained psychologist blinded for treatment allocation. Each individuals performance on the neuropsychologic tests will be compared to his or her performance on the same tests five years earlier, on the day before operation. In accordance to the Statement of Consensus on Assessment of Neurobehavioral Outcomes after Cardiac Surgery the test battery includes tests for motor skills, verbal memory capacity and attention. The principal outcome measure is cognitive decline, defined as a decrease in an individuals performance of at least 20 percent from baseline, in at least 20 percent of the tests.

Secondary outcome measures
1. Quality of life at five years, assessed with the EuroQol10 and ShortForm-3611 questionnaires
2. The occurence of cardiovascular events i.e. mortality, stroke, myocardial infarction and coronary reintervention. Stroke is defined as focal brain injury, detected by standard neurologic examination, persisting for more than 24 hours, combined with an increase in handicap of at least one grade on the Rankin Scale; Myocardial infarction is considered present when two of the following criteria are met: chest discomfort lasting at least 30 minutes, CK-MB/CK ratio >0.1, and the development of abnormal new Q-waves in the electrocardiogram.
3. Anginal status at five years, defined according to the Canadian Cardiovascular Society and Braunwald classification
4. Use of antianginal medication at five years (Beta-blockers, nitrates or calcium entry-blockers)

Overall study start date
01/01/1998

Completion date
31/12/2000

Eligibility

Key inclusion criteria
281 candidates for coronary artery bypass surgery. Patients were eligible if referred for first-time isolated coronary bypass surgery and an off-pump procedure was deemed technically feasible.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
281

Key exclusion criteria

1. Patients were excluded in case of emergency or concomitant major surgery, Q-wave myocardial infarction in the last 6 weeks, or poor left ventricular function.
2. Patients who were unlikely to complete 1-year follow-up, unable to give informed consent, or undergo neuropsychologic testing were excluded.
3. There were no restrictions to age.

Date of first enrolment
01/01/1998

Date of final enrolment
31/12/2000

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht
Utrecht
Netherlands
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Sponsor information

Organisation
International Anesthesia Research Society (USA)

Sponsor details
2 Summit Park Drive, Suite 140
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Sponsor type
Research organisation

ROR
https://ror.org/0252rqe04

Funder(s)

Funder type
Research organisation

Funder Name
International Anesthesia Research Society

Funder Name
Clinical scholar research award 2004

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?
Other publications	rationale and design of the trial:	01/12/2000		Yes	No
Results article	results:	09/10/2001		Yes	No
Results article	results:	20/03/2002		Yes	No
Results article	results:	30/01/2003		Yes	No
Results article	results:	01/04/2004		Yes	No
Results article	results:	21/02/2007		Yes	No