

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

Submission date 24/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/09/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Cor J Kalkman

Contact details
University Medical Centre Utrecht
Dept of Anesthesiology
Heidelbergln 100
Utrecht
Netherlands
3584 CX
-
c.j.kalkman@azu.nl

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

1. Quality of life at five years, assessed with the EuroQol10 and ShortForm-3611 questionnaires
2. The occurrence 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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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
3584 CX

Sponsor information

Organisation

International Anesthesia Research Society (USA)

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

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:	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
Other publications	rationale and design of the trial:	01/12/2000	Yes	No