

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

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<b>Registration date</b> 19/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/09/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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

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 individual's 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 individual's 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 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)

**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

3584 CX

## **Sponsor information**

**Organisation**

International Anesthesia Research Society (USA)

**Sponsor details**

2 Summit Park Drive, Suite 140

Cleveland

United States of America

Ohio 44131

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iarshq@iars.org

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