

The Danish On-pump Off-pump Randomization Study (DOORS): a randomized trial on safety, medical effectiveness and cost-effectiveness of Off-pump Coronary Artery By-pass Surgery.

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Objectives:

To compare the safety and efficacy of coronary artery bypass surgery performed either with or without the use of cardiopulmonary bypass in patients above 70 years of age.

Materials and Methods:

The DOORS Study is a randomized Danish multicentre trial of 900 patients above 70 years, admitted for first time surgical myocardial re-vascularisation in one of the four participating centres. Patients are randomized to undergo coronary artery bypass surgery either with or without the use of CPB. The types of operation, anaesthesia, peri- and postoperative care, and treatment are performed according to predefined, standardized protocols. Patients are followed for three years postoperatively. Primary end-point is death and/or stroke and/or myocardial infarction within 30 days postoperatively. Secondary end-points include patency of by-pass grafts assessed by coronary angiography 6 months after the operation, quality of life assessed by MOS SF-36 and EuroQol questionnaires 6 months and 3 years after the operation, total hospital costs and costs of public care, and difference in costs per quality adjusted life year.

A web-based randomization procedure is used. End-point assessment is performed by an independent committee blinded in regard to the type of operation performed. Graft patency is evaluated by two independent cardiologists according to the FitzGibbon criteria. The principle of intention-to-treat will be used in analyzing the data. An interim analysis will be performed after half of the patients have been recruited. Kaplan-Meier plots will be used for graphic comparisons between groups and log-rank test for numerical comparison.

Results:

Inclusion of patients started January 1st 2005. By april 1st 2006 309 patients were included. Coronary angiography had been performed in 129 patients corresponding to 65% of the patients that had been followed for 6 months. Blinded assessment of the primary end-point and evaluation of graft patency by independent committees are in progress. Patient inclusion is expected to be concluded by the end of 2008.

Conclusions:

The DOORS-study is a randomized multi-centre study comparing coronary artery bypass surgery with or without the use of CPB in 900 patients above 70 years of age. Inclusion and follow-up of patients are in progress.