CABG Off or On Pump Revascularization Study (CORONARY) - a randomized multicenter study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON31836

Source
ToetsingOnline

Brief title
CABG Off or On Pump Revascularization Study (CORONARY)

Condition

- Coronary artery disorders
- Vascular therapeutic procedures

Synonym
coronary artery sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: sponsor bijdragen zijn verzameld door

Population Health Resurch Institue;Mc Master University;Hamilton;Canada

Intervention

Keyword: beating heart, CABG, off-pump, on-pump

Outcome measures

Primary outcome

Primary: In patients undergoing CABG surgery, does off-pump CABG surgery compared to on-pump CABG surgery reduce major clinical vascular events in the short term (30 days) and are the benefits maintained at long term (5 years).

The primary outcome at 30 days is total mortality, stroke, MI and renal failure and at 5 years, the same outcomes plus repeat revascularization.

Secondary outcome

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Secondary: In patients undergoing CABG surgery, does off-pump CABG surgery compared to on-pump CABG surgery reduce costs in the short term (30 days) and at long term (5 years) (cost-effectiveness analysis)?

Study description

Background summary

Conventional coronary artery bypass graft surgery is performed with the help of a cardiopulmonary bypass (CPB) circuit, commonly called *the pump*. CPB allows the surgeon to perform the delicate anastomoses on an arrested heart, under optimal visualization and has been used worldwide in millions of patients. However, the use of CPB during CABG (on-pump CABG) is associated with substantial complications such as cardiac ischemia , stroke , neuro-cognitive dysfunction, renal dysfunction, need for blood transfusions , atrial fibrillation and about 2% perioperative mortality. Overall the rates of these complications are considerable and these events are largely attributed to the CPB itself and to the aortic cannulation and cross-clamping associated with

CPB .

Off-pump CABG does not require hypothermia, CPB, aortic cannulation or cross-clamping of the ascending aorta. Some authors have suggested that off-pump CABG is associated with a significant reduction in atrial fibrillation, renal dysfunction, blood transfusions, length of stay in hospital, overall costs and stroke10. Many small randomized trials have assessed outcomes of off-pump CABG vs. on-pump CABG but these trials had insufficient power to detect moderate but important differences in clinical events such as death, stroke and myocardial infarction (MI). However, given the frequency with which CABG surgery is performed, even moderate reductions in these important clinical complications have a significant health and economic impact.

Study objective

Therefore, there is a real need for a trial to reliably evaluate the short and long term safety and efficacy of off-pump CABG. From a clinical point of view, it is essential to determine if off-pump CABG is associated with a reduction in major perioperative complications (such as CV death, stroke, MI and renal failure) and whether potential long term benefits accrue by avoiding these complications. Alternatively the incomplete revascularization and early graft failure may lead to poorer long term prognosis. Equipoise also exists with respect to the present and future resources implications of the two procedures. Off-pump CABG has the potential to reduce costs of coronary artery surgery in the short term but these savings may not persist in the long term if off-pump CABG is associated with an excess of repeated revascularization procedures.

Study design

A large, prospective, randomized controlled trial with blinded and adjudicated outcome assessments, comparing off-pump CABG versus on-pump CABG .

Intervention

Ptients will be operated either off-pump or by means of a conventional heart-lung machine

Study burden and risks

Not applicable

Contacts

Public
Academisch Medisch Centrum

meibergdreef 9
1100 DE Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

meibergdreef 9
1100 DE Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age 21 year or older
candidate for surgery
presence of one or more risk factors such as DM, peripheral vascular disease

Exclusion criteria

Concommittant cardiac procedure
limited life expectancy

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2008
Enrollment:	600
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	CIHR#171326
CCMO	NL22335.018.08