

Epidural anesthesia for OPCAB, a randomized comparison between general anesthesia alone or general anesthesia combined with high thoracic epidural anesthesia for off pump CABG

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In the present study we will determine the effect of sympathetic blockade by TEA on major outcome parameters after off-pump CABG.

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

Summary

ID

NL-OMON40349

Source

ToetsingOnline

Brief title

Epidural anesthesia for OPCAB: EASYCAB

Condition

- Coronary artery disorders

Synonym

atherosclerosis, Hardening of the arteries

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Geen aparte financiering.

Intervention

Keyword: atherosclerosis, coronary artery bypass, epidural anesthesia

Outcome measures

Primary outcome

The primary endpoint of this study is the composite outcome of 30 days all cause mortality, myocardial infarction, stroke or renal failure requiring dialysis.

Secondary outcome

The secondary endpoints are the separate components of the composite outcome.

Study description

Background summary

Thoracic epidural anesthesia (TEA) with local anesthetics is potentially the preferable anesthetic technique to protect the heart during off pump beating heart surgery against myocardial ischemia. However, the largest trial until now (Anesthesiology 2011; 114:262*70), comparing general anesthesia alone with anesthesia supplemented by TEA did not demonstrate beneficial effects on mortality, myocardial infarction, renal failure or stroke. However, the majority of these patients were operated with the use of heart-lung machine (and aortic cross clamping) and for valve surgery.

Study objective

In the present study we will determine the effect of sympathetic blockade by TEA on major outcome parameters after off-pump CABG.

Study design

This is a randomized, single center , unblinded study, comparing the effect of

general anesthesia with TEA versus general anesthesia alone (TEA versus GA) on the composite outcome of 30 days all cause mortality, myocardial infarction, stroke or renal failure requiring dialysis in patients scheduled for off pump CABG.

Intervention

General anesthesia alone or general anesthesia supplemented by TEA.

Study burden and risks

This is an observational study, comparing two established anesthesia techniques. Obviously, the study itself is without any risk

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Men + Women 18 years or more
- Planned off pump CABG
- life expectancy at least 2 years
- fulfilled the criteria for the anticoagulation status to perform an epidural puncture

Exclusion criteria

- no other off pump procedures planned (such as mini Maze)
- ongoing myocardial infarction or recent myocardial infarction in whom the cardiac enzymes have not returned to normal values
- necessitating intra aortic counter pulsation (left main stenosis)
- chronic renal failure, necessitating dialysis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2015
Enrollment:	1400
Type:	Actual

Ethics review

Approved WMO
Date: 02-09-2014

Application type: First submission
Review commission: METC Twente (Enschede)

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
CCMO	NL47387.044.14