Cardiac Resynchronization Therapy in patients with systolic Heart Failure and mechanical dyssynchrony undergoing Coronary Artery Bypass Grafting

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Inter-individual comparison of the effect of CRT (immediate application of CRT after CABG surgery) on the improvement in left ventricular remodeling, left ventricular function and clinical outcome in patients with systolic heart failure and severe...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON38064

Source
ToetsingOnline

Brief title
CABG-CRT

Condition

- Heart failures

Synonym
Heart Failure, weakened heart muscle

Research involving
Human

Sponsors and support

Primary sponsor: Biotronik

Source(s) of monetary or material Support: Biotronik

Intervention

Keyword: Cardiac Resynchronization Therapy, Coronary Artery Bypas Grafting, Echocardiography, Heart Failure

Outcome measures

Primary outcome

The primary endpoint of the study is to determine whether an improvement in cardiac function (remodeling of the heart and increase the ejection fraction) can be observed in patients with immediate aplication of CRT after CABG surgery.

Secondary outcome

The secondary endpoints will examine the effect of this immediate treatment with CRT on the quality of life (using a QOL questionnaire), the exercise performance (using the 6 minutes walking test), heart failure symptoms (using the NYHA classification), the number of hospital admissions for heart failure and mortality.

Study description

Background summary

Cardiac Resynchronization Therapy (CRT) is a standard therapy for patients with chronic systolic heart failure (LVEF <35% and heart failure symptoms NYHA III-IV) already on optimal medical treatment, with a wide QRS complex on their ECG (> 120 ms) as a measure of electrical dyssynchrony. CRT normalizes in this patient population (through biventricular pacing) the contraction pattern of the heart, which results in an improved cardiac function and clinical outcome as demonstrated in several landmark trials (CareHF, Companion, Miracle, MADIT CRT): reverse remodeling of the heart, improved EF, improvements in exercise capacity and physical activity, improvements in quality of life, reduced

symptoms of heart failure, reduction the number of hospital admissions for heart failure and an improved survival. Ischemic patients undergoing Coronary Artery Bypass Grafting (CABG) surgery have been excluded from these large randomized CRT trials. Currently, no data exist on the impact of CRT in patients requiring revascularization. Penicka and co-workers (Penicka et al, JACC 2007) have recently shown that HF patients with severe left ventricular (LV) mechanical dyssynchrony have a poor outcome after CABG. It is hypothesized that patients with severe LV dyssynchrony would benefit from CRT in addition to surgical revascularization in terms of reverse LV remodeling and improved clinical outcome.

Study objective

Inter-individual comparison of the effect of CRT (immediate application of CRT after CABG surgery) on the improvement in left ventricular remodeling, left ventricular function and clinical outcome in patients with systolic heart failure and severe LV mechanical dyssynchrony who are undergoing CABG surgery.

Study design

prospective
randomized (1:1)
parallel
open label
multicenter
international

Intervention

Patients are randomized into two groups: immediate treatment with CRT or standard medical therapy after CABG surgery. The patients in the "CABG + immediate CRT" group receive during or shortly after CABG surgery a CRT pacemaker (Biventricular Pacemaker). The control group receives standard medical follow-up after CABG surgery and will follow the routine clinical practice.

Study burden and risks

In the treatment group, a CRT pacemaker is implanted during or shortly after the CABG surgery. Potential risks and discomforts associated with this study are those typically related to the implantation of a CRT pacemaker and are explained in the patient information form. The implantation of a biventricular pacemaker is a routine clinical practice in the participating hospital and is only done by cardiologists/surgeons with the necessary experience in the field. The implantation of a CRT pacemaker during the CABG operation will prolong the the surgery time with possible additional risks as a result (increased risk of

infection). If the clinical condition of the patient does not allow a CRT pacemaker to be implanted immediately during the CABG surgery, than the CRT pacemaker will be implanted in a seperate procedure (during the same hospitalization). This is a short procedure corresponding to the implantation of a standard pacemaker.
There are no known risks associated with an ultrasound echocardiography, but there is a potential for a rare anaphylactoid reaction to the contrast agent. This will be discussed with the patient and the treating doctor will provide the necessary precautions. This echocardiogram with the use of contrast agent will be repeated 3 times: baseline, 6 and 12 months after the CABG surgery.
Collection of study-specific data (QOL questionnaire, six minutes walk test, echocardiography, blood sample) is done during the routinely scheduled control visits in line with the normal clinical practice: 1 month, 6 months and 12 months after CABG surgery. Blood sampling during the follow-up visits is a routine practice.

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

Planned CABG surgery
systolic ischemic heart failure despite pharmacological therapy
Left Ventricular Ejection Fraction <= 35%
NYHA II-IV
Intraventricular mechanical delay > 72 ms (to be confirmed by echo corelab)

Exclusion criteria

Myocardial viability < 25%
emergency CABG surgery
Age < 18 years
pregnant or brest feeding woman
previous CRT
permanent or persistant atrial arrhytmias
knwon intolerance to contrast agent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Generic name:	biventricular pacemaker/ICD within intended use of device (with CE label)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-03-2011
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL34437.101.10
Other	registratie bij Clinical Trials.gov is "in progress"