The impact of Early versus Late Complete revascularization On Remodeling of the Left Ventricle in ST-elevation Myocardial Infarction with multivessel disease after primary PCI.

Published: 01-10-2015
Last updated: 13-04-2024

the aim of this study is to compare the impact of an early-CR within 48 hrs. after PPCI to a late complete revascularization >2 weeks after PPCI on LV remodelling in patients with STEMI and multi-vessel disease.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41253

Source
ToetsingOnline

Brief title
Timing of Complete revascularization and left ventricular remodeling

Condition

- Other condition
- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
remodelling of the left ventricle, treatment of multivessel disease

Health condition

hartinfarct, herstel na behandeling van linker kamer

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Complete revascularization, LV-remodeling, multivessel disease, STEMI, timing

Outcome measures

Primary outcome

The primary aim of our study is to assess the association of timing of CR and left ventricular remodelling (increase in end diastolic volume [EDV]>20%) or an increase of at least 5% in left ventricular function after primary PCI in STEMI patients with multi-vessel disease.

Secondary outcome

The secondary objective of our study is to assess the correlation of plasma serum BNP level within the first 24-96 hours of STEMI and the development of subsequent left ventricular dilatation according to CR-group at 3, 6 and 12 months of follow-up on imaging (serial MRI and/or echocardiography) and mortality (all cause and cardiac).

Study description

Background summary

ST-elevation myocardial infarction (STEMI) is a common and the most severe presentation of ischemic coronary disease. Evidence shows a high risk for

mortality and future events in patients with multivessel disease. Based on a large retrospective trial, ESC and ACC/AHA guidelines recommend treatment of culprit lesion only during primary PCI (PPCI). The recent randomized PRAMI study showed a lower MACCE-rate with preventive complete revascularization of non-infarct related arteries (Non-IRA) lesions at PPCI. A reduced global ventricular flow after acute myocardial infarction in non-RA has been suggested to increase the area at risk with poorer left ventricular remodelling in previous research (Gibson et al.). However, the mechanism through which MVD adversely affects outcome is still poorly defined and optimal timing of complete revascularization remains unclear.

Study objective

the aim of this study is to compare the impact of an early-CR within 48 hrs. after PPCI to a late complete revascularization >2 weeks after PPCI on LV remodelling in patients with STEMI and multi-vessel disease.

Study design

prospective study, with sequential allocation

Intervention

After informed consent and immediately after the PPCI patients with multivessel disease will be randomized to either early complete revascularization (CR <48 hr) after PPCI or CR *2 week after PPCI. A FFR will be gauged of all non-IRA lesions to judge functional significance and according to randomization all lesions with a FFR <0.80 will be treated in the same session or in a staged procedure *2 weeks - 4 weeks after PPCI. From patients enrolled in the trial blood will be drawn for the additional assessment of plasma BNP, white blood cell count and HbA1C. Further an echocardiogram and a cardiac MRI (CMR) with delayed enhancement, requiring the infusion of gadolinium, will be acquired within 1-3 days after the PPCI.

Study burden and risks

A short (oral) informed consent will be taken to minimize a delay in the door-to-balloon- time. The usual risks associated with a coronary intervention are also applicable to our study; in <1% of cases death, stroke, ventricular fibrillation, myocardial infarction or aortic dissection may occur. These complications may require a coronary artery bypass surgery. Some bleeding from the insertion point in the groin (femoral artery) is common, but occasionally a hematoma may form. Rarely infection at the puncture site, dissection of the access blood vessel or kidney failure requiring dialysis may occur. Further an allergic reaction to the contrast dye used is possible, but has been reduced with newer agents. During primary PCI patients who are randomized to an

immediate complete revascularization will have a longer procedure and possibly more contrast for the additional treatment of all significant non-IRA lesions during PPCI. This may result in deterioration of the kidney function or above-mentioned procedural complications in a non-IRA. Most of these complications may also occur in an additional procedure. The risk of a complete revascularization is counterbalanced by the fact that a second procedure, which may require re-hospitalization, for significant non-IRA lesions is avoided.
Drug eluting stents (DES) will primarily be used for the treatment of non-IRA lesions and this might require the use of anti-thrombotic therapy for a longer duration. However the final decision for a DES or bare metal stent (BMS) is at the operators* discretion. Further additional blood will be drawn for the assessment of biomarkers of ventricular remodelling (BNP, white blood cell count and HbA1C) within 24 hours of the PPCI. An outpatient visit at 3 months is part of the usual care after discharge in our institute. An additional visit at preferably our outpatient clinic at 6 and 12 months with blood sampling for the follow-up of biomarkers and ventricular remodelling on echocardiogram and/or CMR is required from participants.

Contacts

Public
HagaZiekenhuis

Leyweg 257
Den Haag 2545CH
NL
Scientific
HagaZiekenhuis

Leyweg 257
Den Haag 2545CH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

primary PCI, STEMI, multivessel disease, older than 18 years, hemodynamic stable

Exclusion criteria

cardiogenic shock, resucitation, intra-aortic balloon pump, mechanical ventilation, prior infarction or CABG, life expectancy less than 2 years

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	250
Type:	Anticipated

Ethics review

Not approved

Date:	01-10-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL46738.098.15