Fractional Flow Reserve guide Primary Multivessel Percutaneous Coronary Intervention to Improve Guideline Indexed Actual Standard of Care for Treatment of ST-elevatio Myocardial Infarction in Patients with Multivessel Coronary Disease

Published: 26-05-2011
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FFR-guided complete percutaneous revascularisation of all flow-limiting stenoses in the non-IRA performed within the same procedure as the primary PCI or within the same hospitalisation will improve clinical outcomes compared to the staged...

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

Summary

ID

NL-OMON41311

Source
ToetsingOnline

Brief title
COMPARE-ACUTE

Condition

- Coronary artery disorders

Synonym
STEMI/ multivessel atheromatic -thrombotic coronary obstructions

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: unrestricted grant from Abbott VAscular and Sint Jude Medical

Intervention

Keyword: FFR/ Multivessel PCI/ STelevationMI/, randomisation

Outcome measures

Primary outcome

Composite endpoint of all cause mortality, non-fatal Myocardial Infarction, any

Revascularisation and Stroke (MACCE) at 12 months

Secondary outcome

Primary endpoint at 24 and 36 months as well as outcomes of each component of

the primary endpoint at 12 months.

Primary endpoint rates in the subgroup of patients receiving staged or acute

PCI treatment for FFR positive lesions in the non-IRA vs the subgroup of

patients with FFR positive lesion that received optimal medical treatment

Primary endpoint rates in the subgroup of patients receiving acute PCI

treatment for FFR positive lesions in the non-IRA vs the subgroup of patients

receiving staged PCI treatment for FFR positive lesions in the non-IRA

Primary endpoint rates in the subgroup of patients receiving staged PCI

treatment for FFR negative lesions in the non-IRA vs the subgroup of patients

not receiving PCI treatment for FFR negative lesions in the non-IRA at 3 years.

Composite endpoint of Cardiac death, Myocardial Infarction, any

Revascularisation, Stroke and Major bleeding at 12 months (NACE i.e. Net

Adverse Clinical Events)

Study description

Background summary

At the moment the general opinion is devided over the way the non culprit leasions in patients presenting with STEMI should be treated. While the previous guidelines stead that these leasions should be treated in a second time (ie not during the primary intervention) the actual guidelines do not touch this argument. The reason is that the studies where the previous guidelines were based are old. Meanwhile small sized randomised trials from EU region have proven favourable outcomes with NON infarct related artery during the primary procedure while registers (non randomised trials) from USA still reccomand the staged treatment. For this reason we have decided to performe a randomised studie to address this issue incorporating the state of the art diagnosis and treatment, as well as the new medical therapy and PCI techniques.

Study objective

FFR-guided complete percutaneous revascularisation of all flow-limiting stenoses in the non-IRA performed within the same procedure as the primary PCI or within the same hospitalisation will improve clinical outcomes compared to the staged revascularisation, guided by prove of ischemia or clinical judgment, as recommended from the guidelines

Study design

Prospective, 1: 2 randomisation

FFR guided revascularisation during primary PCI (1)
Following actual guidelines (2)

Intervention

FFR-guided complete percutaneous revascularisation of all flow-limiting stenoses in the non-IRA performed within the same procedure as the primary PCI or within the same hospitalisation will improve clinical outcomes compared to the staged revascularisation, guided by prove of ischemia or clinical judgment, as recommended from the guidelines

Study burden and risks

The risks for the patients are the same for regular PCI

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

STEMI patients, between 18-85 years, who will be treated with primary PCI<12h after the onset of symptoms and have at least one stenosis of >50 % in a non IRA on QCA or visual estimation and judged feasible for treatment with PCI by the operator

Exclusion criteria

Left main stem disease, chronic total occlusion of non-IRA, Severe stenosis with TIMI-flow<3 of the non-IRA artery, non-IRA stenosis not amendable for PCI treatment (operators decision) Killip class 3 and 4, Complicated IRA treatment, STEMI due to in-stent stenosis

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2011
Enrollment:	295
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2011

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-01-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-06-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-05-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL36323.101.11

Study results

Date completed: 31-10-2018

Actual enrolment: 277

Summary results
Trial is onging in other countries