Optimal Timing of Coronary Intervention in Unstable Angina 2

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The objective for this trial is to evaluate an invasive strategy using urgent PCI (

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

Summary

ID

NL-OMON36977

Source
ToetsingOnline

Brief title
OPTIMA 2

Condition

- Coronary artery disorders

Synonym
heart attack, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Cardiologie
Source(s) of monetary or material Support: De research BV Cardiologie OLVG

Intervention

Keyword: Acute coronary syndrome, NSTEMI, PCI, Timing

Outcome measures

Primary outcome

The primary endpoint will be:

Size of MI during initial hospitalization as measured by the AUC of CK-MB.

Secondary outcome

The secondary endpoints of this trial are:

- Size of MI during initial hospitalization as measured by the AUC of CK-MB for the subpopulation of patients treated with PCI
- The composite endpoint of death, MI and unplanned revascularization at 30 days
- The composite endpoint of MI and major haemorrhage
- Incidence of major haemorrhage up to 30 days
- Incidence of minor haemorrhage up to 30 days
- Incidence of individual and composite endpoints at 30 days and 6 and 12 months including recurrent NSTE-ACS
- Any revascularisation and/or restenosis (TVR) up to 6 months
- Re-hospitalisation because of coronary artery disease (CAD)

Several prespecified sub-analyses will be performed.

- Time of hospitalization
- Hospital costs
- Size of MI during initial hospitalization as measured by the AUC of hsTnT
- Size of MI during initial hospitalization as measured by the AUC of hsTnT for the subpopulation of patients treated with PCI.

- Comparison of left ventricular function will be performed using longitudinal

strain measurements as derived by 2D echocardiography

- Change in left ventricular function as assessed by using longitudinal strain

measurements between the groups will be evaluated.

- The specificity of NT-proBNP for MI will be evaluated when using hsTnT samples

- The multimarker approach using hsTnT, NT-proBNP and CRP will be evaluated

with regard to the prediction of clinical events

Study description

Background summary

The question when to perform PCI in patients with NSTE-ACS has been the subject of much discussion for patients with non-ST elevated acute coronary syndrom. Among initially stabilized patients optimal timing of angiography had not been well defined. The last few years several studies have evaluated the influence of timing of intervention in these patients. However, comparison of data and interpretation of the results are difficult, mainly due to methodological differences between the studies.

Findings from previous trials suggest that angiography performed within 72 hours after admittance is associated with a lower re-mi rate. Still they do not provide support for undertaking a race against time to perform angiography, as is justified in STEMI cases.
The time-event relationship with ACS could therefore take the form of a *U* shaped curve, with very short and very long times to angiography posing a risk. However, previous trials are conducted with earlier generations of antiplatelet therapy. Since now there is a novel antiplatelet therapy which is acting faster and stronger the so called "U" shape might not be accurate anymore. Novel antiplatelet therapy, such as ticagrelor, is acting faster tot passificate the coronary plaque, so PCI for patients with ST-elevated myocardial infarction could be performed earlier without the risk of increase in periprocedural complications.

This current trial is designed to evaluate the protective effect of the current generation antiplatelet therapy, in combination with other modern anticoaglulants which are used as standard of care in patients admitted with a

non-ST elevated myocardial infarction.

Study objective

The objective for this trial is to evaluate an invasive strategy using urgent PCI (<3h) as compared to an early PCI (24h) using novel quick acting antiplatelet therapy.

Study design

This is a randomised, prospective, open-label and single center study, for patients admitted to the hospital with the diagnosis of a non-ST elevation myocardial infarction. The additional procedures are according to the standard methods of percutaneous coronary intervention.

Intervention

Revascularisation (where necessary) by percutaneous coronary revascularisation: Randomised to either "urgent" (<3 uur) or "early" (12-24 uur) angiography/PCI.

Study burden and risks

It is unclear whether urgent angiography and PCI for patients with non-ST elevated myocardial infarction after they received Ticagrelor will lead to better (clinical) outcomes. However, by making use of novel antiplatelet therapy this theory is plausible, as is described above. Currently there are no trials showing that this group of patients benefit by urgent revascularisation. Because of this it might be possible that patients will not benefit or urgent revascularisation will even have a negative effect on patients (clinical) outcome.

Patient who will participate in OPTIMA-2 will undergo additional bloodsampling during hospitalization as compared to patients who do not participate.
The study includes three extra outpatient visits for study purposes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age > 21 years
- Typical chest pain for angina pectoris lasting at least 10 minutes, within the
last 24 hours
- No contra-indication to PCI
- And at least one of the following criteria:
1. 1 mm of horizontal or downsloping ST depression
2. Dynamic ST- or T- wave changes > 1 mm in two contiguous leads
3. Elevated hs troponin (>1xULN)
4. Known coronary artery disease
5. Two of following risk factors: DM, known hypertension, current smoking, family history for ischemic heart disease, hypercholesterolemia, peripheral artery disease, age over 60 years.

Exclusion criteria

- Acute ST myocardial infarction
- Refractory angina
- Severe heart failure
- Life-threatening ventricular arrhythmias
- Haemodynamic instability
- Contraindication for the use of Ticagrelor

- Participation in another study
- Use of oral anticoagulants

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2012
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-08-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-06-2024

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	NL41414.100.12