Prevention of Late Stent Thrombosis by an Interdisciplinary Global European effort

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1) To identify new predictors of ST, in particular of late and very late ST, and of drug eltuing stent thrombosis. 2) To observe clinical outcomes after an episode of ST.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON47161

Source
ToetsingOnline

Brief title
PRESTIGE

Condition

- Coronary artery disorders

Synonym
in-stent thrombosis; blood clot in previously implanted coronary stent

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: percutanous coronary intervention, platelet function, stent thrombosis

Outcome measures

Primary outcome

Clinical, biochemical, angiographic, procedural, haematological,

histopathological, genetic, visual (by means of OCT/IVUS) and follow-up

characteristics.

Secondary outcome

Not applicable.

Study description

Background summary

Stent thrombosis (ST) is a serious complication of percutaneous coronary intervention (PCI) with stent implantation. Stent thrombosis complicates approximately 0.5-4% of all PCI's and is associated with high morbidity (recurrence myocardial infarction, poor left ventricular function and recurrence ST) and high mortality rates.

Further research after ST is urgently needed, to identify those patients at high risk and to gain more insight in the pathophysiology of ST. However, previous studies after ST have been hampered by a small sample size and small numbers of patients with late and very late ST' and 'drug eluting' stent thrombosis.

Study objective

1) To identify new predictors of ST, in particular of late and very late ST, and of drug eltuing stent thrombosis.
2) To observe clinical outcomes after an episode of ST.

Study design

Multicenter, matched case-control study

Study burden and risks

Patients presenting with ST will undergo PCI according best clinical practice of institutional standards. 50 mL blood will be collected from all patients. When thrombosuction is performed, the thrombus will be collected and analysed. Performance of OCT/IVUS will be encouraged. During hospitalisation, patients will be asked to fulfill a questionnaire regarding potential triggering mechanisms of ST. Patients will be asked to visit the outpatient clinic 30-60 days after the acute phase for blood sampling and urine collection in order to perform blood platelet function testing. Finally, patients will be contacted 30 days, 1, 2, and 3 years after ST for follow-up information.
The risks for patients when participating this study will be little. Performance of OCT/IVUS can result in 'chest discomfort', however, with the improvement of the equipment it can be expected that this risk will decline. Advantages of OCT/IVUS performance for the patient can possibly be a more accurate implantation of the stent and better PCI results.

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

Cases: all patients suffering a stent thrombosis
Controls: patients without ST who underwent PCI with stent implantation on the same date (±5 days) of index PCI of matched case, in the same interventional centre and with the same indication will be enrolled.

Exclusion criteria

Absence of an informed consent;If a case or matched control patient dies before written Informed Consent could be obtained the clinical data will be used for the study, but only if the researcher doesn*t have any suggestion that the patient would have declined his consent if he still would have been alive. The researcher will write a note in the CRF stating this assumption. The family will not be contacted and no blood samples will be stored.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2011
Enrollment:	3000
Type:	Actual

Medical products/devices used

Generic name:	Optical Coherence Tomography / Intravascular Ultrasound
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-06-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-05-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-10-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	09-07-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-10-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-07-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-03-2018
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	NL36259.100.11