The National Dutch Stent Thrombosis Registry

Published: 29-06-2017
Last updated: 16-04-2024

1) To identify new predictors of ST, especially 'late' and 'very late ST', 'drug eluting ST' and 'bio-absorbable scaffold thrombosis'.2) To observe clinical outcome after an episode of ST

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

Summary

ID

NL-OMON47084

Source
ToetsingOnline

Brief title
National DUST

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: Het St. Antonius Onderzoeksfonds,St. Jude Medical

Intervention

Keyword: Percutaneous coronary intervention, Stent thrombosis, Stents

Outcome measures

Primary outcome

Clinical, angiographic, procedural, hematological, histopathological, genetic,

visual (by means of OCT) en 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. ST has a major clinical impact with a high risk of myocardial infarction (MI) in 80% of the cases and death in 12% to 40% of the cases. Further research is urgently needed to identify those patients at high risk and to gain insight in the pathophysiology of ST. Previous studies have been hampered by small sample size, in particular regarding the number of patients with 'late' (>30 days after stent implantation) and 'very late ST'(>12 months after stent implantation), patients with drug-eluting stent thrombosis and bio-absorbable scaffhold thrombosis.

Study objective

1) To identify new predictors of ST, especially 'late' and 'very late ST', 'drug eluting ST' and 'bio-absorbable scaffold thrombosis'.
2) To observe clinical outcome after an episode of ST

Study design

Multicenter prospective registry study

Study burden and risks

Patients presenting with ST will undergo PCI according the best clinical

practice of institutional standards. 4.5 - 6 ML of blood will be collected from all patients, when this is not possible during PCI, blood will be collected after the procedure via venipuncture. When thrombus aspiration is performed, the thrombus will be collected for future analysis. Performance of OCT will be encouraged. During hospitalisation, patients will be asked to fill in a questionnaire regarding potential triggering mechanisms of ST. Finally, patients will be contacted (if necessary) 1, 2 and 3 years after ST for follow-up information. The risks are considered relatively low for patients, when participating in this study. Performance of OCT can result in chest discomfort, however it is expected that this risk will decline with the new systems with high speed pullbacks that permit coronary imaging in a few seconds. Possible advantages of OCT performance for the patient are 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 stent thrombosis who underwent PCI with stent implantation on the same date (± 14 days) of index PCI of matched cases, in the same interventional centre and with the same indication as the matched cases will be enrolled.

Exclusion criteria

The absence of an informed consent (IC).
If a case patient dies before written IC could be obtained, the clinical data will be used for the study only if the researcher does not have any suggestion that the patient would have declined his consent if he would still be alive. The researcher will make 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:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-10-2017
Enrollment:	1000
Type:	Actual

Medical products/devices used

Generic name:	Optical coherence tomography (OCT) and Export Aspiration Catheter (for thrombus aspiration / removal

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-06-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-10-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-11-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-11-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-01-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-01-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-02-2019
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-06-2020
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	NL57084.100.16