

# The National Dutch Stent Thrombosis Registry

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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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Coronary artery disorders
<b>Study type</b>	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 scaffold 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 ( $\pm 14$  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)
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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