the Dutch Stent Thrombosis Study

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1) identifying new predictors of ST, in particular of late and very late ST and drug eluting stent thrombosis2) to observe clinical outcome after an episode of a ST

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

Summary

ID

NL-OMON39367

Source
ToetsingOnline

Brief title
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: eigen onderzoek

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) and follow-up

characteristics

Secondary outcome

Bleedings according to the TIMI criteria

Study description

Background summary

Stent thrombosis (ST) is a serieus complication of percutaneous coronary interventions (PCI) with stent implantation. Stent thrombosis complicates approximately 2-4 % of alle PCI's en is associated with high morbidity and mortality rates. Further research after stent thrombosis is urgently needed, to identify those patients at risk en to gain more insigh in the pathophysiology of ST. However, previous studies after ST have been hampered by a small sample size en small numbers of patients with 'drug eluting' stent thrombosis and late and very late ST.

Study objective

1) identifying new predictors of ST, in particular of late and very late ST and drug eluting stent thrombosis
2) to observe clinical outcome after an episode of a ST

Study design

multicenter, matched case control study

Study burden and risks

During PCI (according to institutional standards), 50 mL of blood will be collected of all patients. Performance of OCT (when indicated) is encouraged. Consequently, thrombus will be aspirated from the coronary artery.
During hospitalisation, patients will be asked to fulfill a questionnaire

regarding potential triggering mechanisms of ST. Patients will be asked to visit the hospital after the acute phase to donate blood in order to perform platelet function testing. Finally, patients will be contacted for followup details.
Patients which will be included retrospectively, will be asked to visit the hospital once for blood donating. When they do not want to visit the hospital they will be asked to donate saliva via saliva containers for DNA donating. These saliva containers will be sent to their homes and they can send it back to the hospital for free.

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

all patients suffering a stent thrombosis

Exclusion criteria

Abcense 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:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2010
Enrollment:	4000
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	02-03-2010
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-08-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-02-2012
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:	02-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-10-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-11-2014
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	NL29798.100.09