The Feasibility and Safety of Optical Coherence Tomography Guided Thrombus Aspiration in Patients With Initial Conservative Management of Non-ST-Elevation Myocardial Infarction

Published: 04-05-2010
Last updated: 03-05-2024

The objective of the study is to assess the feasibility and diagnostic yield of OCT guided thrombus aspiration in patients presenting with initial conservative management of non-ST-elevation myocardial infarction (NSTEMI).

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

Summary

ID

NL-OMON36290

Source
ToetsingOnline

Brief title
OCT guided thrombus aspiration

Condition

- Coronary artery disorders

Synonym
heart attack, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: angioplasty, myocardial infarction, therapy, thrombus aspiration

Outcome measures

Primary outcome

The rate of effective thrombus aspiration as determined by histopathological examination, the residual thrombus load on OCT after thrombus aspiration and stent implantation

Secondary outcome

Improvement of angiographic parameters (thrombosis in myocardial infarction flow grade, myocardial blush grade, distal embolization), and clinical outcomes (death, myocardial infarction, target vessel revascularization 30 days after the procedure).

Study description

Background summary

Embolization of atherothrombotic material is common during percutaneous coronary intervention (PCI) in patients with acute coronary syndromes (ACS). This may lead to occlusion of distal vessels resulting in impaired myocardial perfusion, which is associated with larger infarct size and increased mortality. Optical coherence tomography (OCT) is a new imaging modality allowing invasive assessment of coronary artery thrombus load before and after the PCI.

Study objective

The objective of the study is to assess the feasibility and diagnostic yield of

OCT guided thrombus aspiration in patients presenting with initial conservative management of non-ST-elevation myocardial infarction (NSTEMI).

Study design

A pilot study.

Study burden and risks

Based on currently available clinical evidence risks related to the devices used in this study is comparable to standard equipment used for conventional PCI.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Chest pain suggestive for myocardial ischemia for at least 30 minutes,
- Electrocardiogram (ECG) with ST- segment shifts (ST-segment depression >1 mm in at least two contiguous leads or transient ST-segment elevation >1 mm with duration of <30 min in at least two contiguous leads) and/or T-wave changes (T-wave inversion >1.5 mm in at least three contiguous leads),
- Positive troponin T >0,04 µg/L.
- Time between the onset of last symptoms and PCI of more than 12 hours and shorter than 7 days,
- initial conservative management (e.g. asprin, heparine, statins)
- The presence of one ischemia-related target lesion on invasive coronary angiography with a clinical indication for PCI,
- TIMI flow grade of 2 or higher,
- Vessel suitable for 2.25 mm diameter or larger stent implantation,
- Informed consent.

Exclusion criteria

- Persistent ST-elevation of > 1 mm in 2 or more leads,
- TIMI 0 or 1 flow on coronary angiography,
- Need for emergency coronary artery bypass grafting,
- Presence of cardiogenic shock,
- Preexisting life-threatening disease with a life expectancy of less than 6 months,
- Creatinine > 200 µmol/l before the procedure,
- Inability to provide informed consent.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	08-06-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	04-05-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-07-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL31609.042.10