Bifurcation Lesion Analysis and Stenting

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Primary Objective: To demonstrate that IVUS with VH guidance leads to better post procedural outcome when compared to angiographic guidance only.Secondary Objective:To demonstrate that IVUS and VH guidance leads to lower occurrence of MACE at short...

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

Summary

ID

NL-OMON33545

Source
ToetsingOnline

Brief title
BLAST

Condition

- Coronary artery disorders

Synonym
atherosclerotic plaque, coronary disease

Research involving
Human

Sponsors and support

Primary sponsor: Volcano Europe SA/NV
Source(s) of monetary or material Support: Sponsor

Intervention

Keyword: Bifurcation lesions, Coronary angioplasty, Drug Eluting Stent

Outcome measures

Primary outcome

Baseline demographics and anatomy will be displayed comparing the two treatment groups: angiogram only and angiogram with VH-IVUS.

The three primary endpoints: correct identification of calcium presence, accurate measurement of lesion length for stent sizing, and correct minimal lumen CSA will be used to determine overall improved diagnostic accuracy.

Secondary outcome

Niet van toepassing

Study description

Background summary

Bifurcation lesions have a higher rate of restenosis and procedural complications than non-bifurcation lesions and are associated with increased risk for late stent thrombosis (LST). Fibroatheromas, repeated plaque ruptures, and plaque progression are known to take place at low shear stress locations and are thus a common finding at bifurcations. The location can vary from proximal part of the bifurcation to the mid or even more distal location depending on the stage of the disease, spatial orientation of the branching arteries, and flow dynamics.

Different plaque types correlate with vessel remodeling. Lesion rich with necrotic core, such as thin cap fibroatheromas, are associated with sudden coronary death, can be positively remodeled and thus be angiographically silent. Fibrofatty and fibrotic plaque compositions have been show to correlate with plaque shift during balloon angioplasty. On the other hand, in lesions rich with necrotic core, the necrotic core has been shown to be released into the lumen during balloon angioplasty. A statistically significant, positive correlation has been shown with the amount of necrotic core and the amount of distal embolization (increase CK-MB and troponin I rise after stenting).

The first objective of this study is to demonstrate that pre-intervention grayscale IVUS with VH can provide more accurate information on lesion characteristics than information derived from pre-procedural angiogram only.

The second objectives of this study are to demonstrate that grayscale IVUS with VH during and post intervention can guide to better procedural and long-term outcome when compared to angiographic guidance only.

Study objective

Primary Objective:
To demonstrate that IVUS with VH guidance leads to better post procedural outcome when compared to angiographic guidance only.

Secondary Objective:
To demonstrate that IVUS and VH guidance leads to lower occurrence of MACE at short (30 days) and/or long term (2 years) when compared to angiographic guidance alone. With regard to VH IVUS, special attention will be paid to the impact of un- or partially covered confluent necrotic core against lumen surface on long term clinical outcomes.

Tertiary Objective:
To demonstrate that grayscale with VH IVUS are more advanced diagnostic techniques to provide pre- interventional knowledge of the amount, composition, and location of the atherosclerotic plaque when compared to information provided by pre-procedural angiogram.

Study design

Global, multi-center prospective, two-arm (blinded to IVUS grayscale and VH-IVUS information vs. non-blinded), randomized study.

Intervention

The patient is scheduled for intervention of coronary bifurcation lesion using DES stents

Study burden and risks

IVUS is a diagnostic technology, where a catheter is advanced into the coronary artery. This additional step during the procedure will take some additional treatment time (several minutes). The risks for using IVUS are identical as for interventional procedures in general (such as bleeding at the entry puncture site, injury to the vascular wall, thrombosis of
the vessel, and peripheral embolization).

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

1. Patient must be greater than 18 years of age.
2. Patient is scheduled for coronary stenting of a bifurcation lesion in a native artery using Drug Eluting Stents.
3. Patient must be willing and able to read and sign the informed consent document before planned coronary intervention.
4. If the patient is female and of child bearing potential, a pregnancy test (serum HcG or urine dip stick) is negative within 7 days of the procedure.
5. Side branch lumen diameter min of >2 mm by visual, angiographic estimate.
6. Patient must agree to be available for follow-up at 30 days, 1 and 2 years after procedure.
7. Other significant lesions in different vessels should be treated successfully (residual stenosis < 30%, normal TIMI flow, no EKG modification) before treating the index bifurcation lesion.

Exclusion criteria

1. The patient experiences significant hepatic disease, renal disease, lung disease and/or malignant disease with unfavorable prognosis.
2. Any contraindications for IVUS interrogation as determined by the investigator including sever vessel tortuosity and severe calcification by angiogram.
The patient suffered a cerebrovascular accident within the past 6 months and has residual effects from the event.
3. The patient suffered significant (as determined by the Investigator) gastrointestinal bleeding within the past 3 months.
4. The most recent white blood cell count less than 3,000 cell/mm3 or the number of platelet is less than 100,000 cell/mm3.
5. The patient has contraindication to antithrombotic regimen or anticoagulation therapy.
6. The lesion is 0.0.1. (Medina classification).
7. The bifurcation lesion involves an anastamosis site from previous a coronary artery bypass surgery.
8. Acute MI or recent MI with CPK > 3 times the normal value prior to intervention (during index hospitalization).
9. Other significant lesion in the same vessel.
10. Other lesion in a different vessel not successfully treated.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2009
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	16-10-2008
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL24260.044.08