Validation of stent boosting versus intravascular ultrasound for assessing optimum deployment of coronary stents

Published: 05-11-2007
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Validation of stent boosting technique for optimum stent deployment compared to intravascular ultrasound (IVUS).

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

Summary

ID

NL-OMON31367

Source
ToetsingOnline

Brief title
Stent boosting versus IVUS

Condition

- Coronary artery disorders

Synonym
Insufficient stent deployment

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Medtronic ,Medtronic B.V.

Intervention

Keyword: coronary stents, Intravascular ultrasound, optimum deployment, Stent boosting, stent thrombosis

Outcome measures

Primary outcome

Optimum stent deployment according to the established criteria as described in

the appendix of the protocol.

Secondary outcome

Not applicable.

Study description

Background summary

Validation of stent boosting versus intravascular ultrasound for assessing optimum deployment of coronary stents.

Study objective

Validation of stent boosting technique for optimum stent deployment compared to intravascular ultrasound (IVUS).

Study design

In 2 groups of 30 patients, stent deployment will be investigated by both techniques.
One group consists of these patients in whom stent boosting indicates optimum deployment; the other group in whom it indicates suboptimal deployment.

Study burden and risks

In patients in whom stent implantation needs to be performed anyway, the IVUS catheter will be introduced over the existing wire. This will prolong the procedure with 15 minutes and the associated risk is very low compared to the procedure of stent implantation in itself.

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

Patients undergoing stent implantation.

Exclusion criteria

Any unstable condition.
Small or toruous coronary arteries.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2007
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	05-11-2007
Application type:	First submission
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	NL19145.060.07