Clinical evaluation of Alpine® vs. Xpedition® stent delivery system of the XIENCE® everolimus-eluting stent

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To evaluate and compare the procedural time of two stent delivery systems for PCI with EES.

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

Summary

ID

NL-OMON45629

Source
ToetsingOnline

Brief title
AXES

Condition

- Coronary artery disorders

Synonym
obstruction in the arteries that supply the heart with blood, significant coronary stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Abbott B.V.,Bedrijven

Intervention

Keyword: everolimus-eluting stent, percutaneous coronary intervention, procedural time, stent delivery system

Outcome measures

Primary outcome

The primary endpoint is the proportion of procedures with crossing time (from introduction of guidewire to stent deployment) longer than 30 minutes.

Secondary outcome

Secondary endpoints include procedural time (from heparin administration to removal of catheter sheath, mins), use of additional materials, total procedural costs, radiation dose (*Gym2), radiation time (mins), and contrast dose (ml).

Study description

Background summary

The current gold standard for percutaneous coronary intervention (PCI) is the second generation drug-eluting stent (DES). The most commonly used DES is the everolimus-eluting stent (EES). New stent delivery systems for PCI with EES are developed to optimize strength, flexibility and pushability of the catheter.
The effect of new stent delivery systems on procedural time has not yet been investigated in clinical practice.

Study objective

To evaluate and compare the procedural time of two stent delivery systems for PCI with EES.

Study design

Randomized comparative trial with 500 patients in the University Medical Center Groningen (UMCG).

Intervention

The first group will undergo PCI with the XIENCE EES using the Alpine stent delivery system, the second group will undergo PCI with the Xpedition stent delivery system.

Study burden and risks

Both stent delivery systems have received CE marking, are commercially available and are used within their indication. Both stent delivery systems use identical stents, meaning that the treatment given to both study groups is equivalent and patients will not be exposed to additional burdens or risks.

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 undergoing PCI with EES, aged 18 years or older, will be considered for eligibility.

Exclusion criteria

Patients will be excluded when scheduled for chronic total occlusion (CTO) PCI or if verbal informed consent cannot be obtained.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2017
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	25-07-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	24-05-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-09-2018
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	NL60872.042.17