The Real-World Endeavor Resolute versus Xience V Drug-Eluting Stent Study in Twente

Published: 22-05-2008
Last updated: 07-05-2024

Primary research questions:* To investigate whether the clinical outcome following the randomized implantation of the Endeavor Resolute® versus XIENCE V® drug-eluting stent is similar, as assessed in a non-inferiority setting by comparing target-...

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

Summary

ID

NL-OMON32057

Source
ToetsingOnline

Brief title
TWENTE trial

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Arterio sclerose, hardening of the arteries

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Stichting Hartcentrum Twente

Intervention

Keyword: Coronary disease, Drug-eluting stent, Percutaneuous Coronary Intervention

Outcome measures

Primary outcome

* Target vessel failure (TVF) at 12 months (according to ARC definitions)

Components of the primary endpoint in hierarchical order:

* Target vessel related death or cardiac death that cannot be clearly attributed to a vessel other than the target vessel. All deaths are considered cardiac, unless an unequivocal noncardiac cause can be established.

* Target vessel related MI (n,%), that is Q-wave or non-Q-wave myocardial infarction that can be related to the target vessel or cannot be related to another vessel.

* Clinically driven repeated target vessel revascularization by means of CABG or PCI (n,%)

Secondary outcome

• Clinical endpoints at one and three month and 1,2,3,5 year follow-up (with the exception of TVF at 1 year which is the primary endpoint, as described above):

o Death

o Any myocardial infarction

o Any revascularisation by means of PCI or Coronary Artery Bypass Grafting (CABG).

o Target vessel related death

o Target vessel related myocardial infarction

o Clinically indicated repeated target vessel revascularization (TVR)

o Clinically indicated repeated target lesion revascularization (TLR)

o New onset of angina pectoris

o Stent thrombosis (Definite, Probable, and Possible; ARC definition):

• Composite endpoint at one month and 1,2,3,5 year follow-up (except TVF at one year follow-up which is already the primary endpoint) :

o Target vessel failure (TVF) as defined above.

o Major Adverse Cardiac Events (MACE), patient oriented

o MACE, device/lesion oriented

• Angiographic endpoints in entire population at final angiographic assessment.

• A substudy will include angiographic endpoints in subpopulation of patients referred for angiographic re-evaluation and in subpopulation of these patients who will require re-intervention e.g. clinically indicated angiographic re-evaluation.

• In subgroup of patients with clinically indicated Intravascular ultrasound (IVUS) endpoints will be assessed

Study description

Background summary

At this moment, most interventional cardiologists in Europe consider both, the Endeavor Resolute stent and the XIENCE V stent as promising second-generation DES. The current medical literature does not suggest that one of these DES may be superior to the other. In agreement with the general trend in Europe, the

interventional cardiologists at MST use both of these DES in routine clinical practice. In fact, the Endeavor Resolute stent and the XIENCE V stent are already used *at random* at our center.
Instead of unintentionally choosing one of these second-generation DES, we would like to randomize the use of these two second-generation DES in patients, who should be stented with DES anyway. This would allow us to obtain valuable scientific data, which permit a head-to-head comparison of these two DES with regards to the clinical outcome in a real world scenario. In addition, efficacy, safety, and acute angiographic results of the implantation of both stents can be compared. Accordingly, we designed the protocol of the TWENTE Study - a study which intends to evaluate the clinical outcome of randomized application of two second-generation drug-eluting stents (Endeavor Resolute stent vs. XIENCE V stent) in a non-selected population of patients who undergo PCI with use of DES implantation.

Study objective

Primary research questions:
* To investigate whether the clinical outcome following the randomized implantation of the Endeavor Resolute® versus XIENCE V® drug-eluting stent is similar, as assessed in a non-inferiority setting by comparing target-vessel failure (TVF) of both stents. In brief, we want to compare for both drug-eluting stents the combined endpoint of death, myocardial infarction or revascularization related to the target-vessel, as well as death or myocardial infarction that cannot be related to a significant flow obstruction in another vessel or to another cause.

Secondary research questions:
* We want to compare the effectivity, safety, clinical short- and long-term outcome, and the acute angiographic results of the implantation of two second-generation drug-eluting stents in a real world scenario. Angiographic comparison will be based on the routine Angiography runs recorded during routine diagnostic coronary angiography and routine angiography runs during PCI procedures. No additional angiographic studies are required.

Study design

Randomized study comparing the clinical outcomes of two CE-certified second-generation drug-eluting stents: the Endeavor Resolute stent and XIENCE V stent.

Study burden and risks

Patients will receive the routine treatment provided in our center. As a consequence, the risks of this trial do not exceed the risks of any routine PCI procedure at Medisch Spectrum Twente, because the PCIs in this Study will not

deviate in any way from the local clinical routine.

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

* Indication for PCI with DES implantation based on NVVC/ESC guidelines and/or clinical decision of interventional cardiologist
* Age >= 18 years and mentally capable to give an informed consent
* Signed informed consent

Exclusion criteria

* Patients with ST-elevation myocardial infarction (STEMI) or an ST-elevation myocardial infarction equivalent requiring primary PCI or rescue PCI
* Patients in whom the revascularization procedure is planed to be performed in a staged approach
* Renal failure requiring haemodialysis
* Patient is currently participating in an investigational drug or device study that has been not completed
* Life expectancy less than 1 year

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2008
Enrollment:	1380
Type:	Actual

Ethics review

Approved WMO Date:	22-05-2008
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-09-2011
Application type:	Amendment

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	NL22222.044.08