New TiDES-ACS Trial

Randomised Comparison of Titanium-Nitride-Oxide Coated Bio-Active-Stent (OPTiMAX™-BAS) vs. Bioabsorbable Polymer Everolimus Eluting Stent (SYNERGY™-DES) in Acute Coronary Syndrome

12-MONTH DATA RELEASE

INNOVATIVE SOLUTIONS FOR CARDIOVASCULAR HEALTH

Having launched their 1st coronary stent in the late 90’s, HEXACATH has been committed to developing a complete range of high-technology products in the field of angioplasty. These cutting-edge devices are the fruit of their long-standing partnerships with key opinion leaders, laboratories, and physicians from around the world.

HEXACATH created in the Paris area of France
Launch of HELISTENT™ Bare Metal Stent
Launch of TITAN™ Bio Active Stent
Launch of TITAN2™ Bio Active Stent
Launch of OPTiMAX™ TiNO coated 3rd generation Stent

R&D collaboration programme established
Manufacturing facility inauguration in Morteau, France
Late Breaking Trial TITAX-AMI Randomised Trial (TiNO stent vs. PES)
Late Breaking Trial BASE-ACS Randomised Trial (TiNO stent vs. EES)

ESC CONGRESS 2017
Late Breaking Science TIDES-ACS Randomised Trial (TiNO stent vs. EES latest gen.)

HEXACATH’s research and development programme is dedicated to bringing the most innovative solutions for patients’ cardiovascular health.
The important role of stent surface material

Despite the advances that drug-eluting stents have brought to interventional cardiology, their use has presented some constraints for patients including the requirement to take aspirin/clopidogrel to reduce the risk of late stent thrombosis, loss of vasomotion, hypersensitivity reactions, and risk of late restenosis. Research reveals that stent surface material importantly affects neointimal hyperplasia and thus restenosis.

The New OPTiMAX™ surface NO-particles stent

+ 70% TiNOX coating
Enhanced PVD technology allows thicker titanium-nitride-oxide coating

Thinner struts by 20%
Cobalt chromium alloy reduces strut thickness from 90 to 75 microns versus steel alloy TITANZ™

Benefits of surface NO-particles

Previous investigations have shown that NO prevents platelet aggregation and reduces proliferation of smooth muscle cells.

Stent coating with titanium-nitride-oxide is associated with NO-particles on the stent surface promoting:

- Prevention of platelet aggregation and fibrinogen binding
- Reduced proliferation of smooth muscle cells
- Minimised risk of thrombus formation
- Reduced risk of late luminal loss and restenosis

SURFACE NO STENT: A SAFE ALTERNATIVE TO DES?

Why the TIDES-ACS Trial?

Early generation drug-eluting stents have reduced restenosis, but have been associated with an increased risk of late stent thrombosis

Titanium-Nitride-Oxide coating has been shown to decrease inflammatory reaction as well as platelet aggregation and is associated with accelerated re-endothelialisation, thus reducing neointimal formation as well as thrombotic risks

Larger trial was required to better assess the benefits of Titanium-Nitride-Oxide (TiNO) on the endothelial healing process post angioplasty

NON-INFERIORITY RANDOMISED TRIALS WITH TiNO coated stents vs. DES

TITAX-AMI
Demonstrated non-inferiority at 12 months and significantly less MI or Cardiac Death and Stent Thrombosis at 24 months of TiTAN2™ vs. TAXUS™ LIBERTÉ™

BASE-ACS
Demonstrated non-inferiority at 12 months and significantly less MI or Cardiac Death and Stent Thrombosis at 60 months of TiTAN2™ vs. Xience V®-EES

TIDES-ACS
Comparing OPTiMAX™ to the latest bioabsorbable polymer Everolimus Eluting Stent

Comparison of Titanium–Nitride-Oxide coated Stent (OPTiMAX™-BAS) versus Bioabsorbable Polymer Everolimus Eluting Stent (SYNERGY™-DES)

This prospective, randomised and multicenter trial compared the clinical outcome in patients presenting with ACS, treated with PCI using OPTiMAX™ versus SYNERGY™.

Primary Endpoint:
MACE at 12 months: the composite of cardiac death, myocardial infarction (MI) and target lesion revascularisation (TLR) during 12 months of follow-up (non-inferiority).
8.5% (α = 5%; β = 90%; delta [non-inferiority margin] = 3.5%)

Inclusion Criteria
Acute coronary syndrome adult patients with:
• Non ST-elevation acute coronary syndrome (NSTEMI)
• ST-elevation myocardial infarction (STEMI)
• Unstable angina
OPTiMAX™: demonstrated non-inferiority vs. 3rd generation Drug-Eluting Stent

MACE at 12 months with OPTiMAX™ stent vs. SYNERGY™ stent

6.3% OPTiMAX™ (n=989) vs. 7.0% SYNERGY™ (n=502)

(HR 1.12; 95% CI 0.73 – 1.72; \( p_{\text{non-inferiority}} < 0.001, p_{\text{superiority}} = 0.66 \))

Non-inferiority zone
Pre-specified margin = 3.5%

-3.0 -2.0 -1.0 0 1.0 2.0 3.0 4.0

Favours OPTiMAX™ 3.5 Favours SYNERGY™

Mean age of randomised patients was 63 years old with 76% being males.
Analysis conducted in intention-to-treat population; 12-month follow-up available in 99.3% of patients.

OPTiMAX™ stent met the primary endpoint of non-inferiority to platinum-chromium-based bioabsorbable-polymer EES for MACE at 12 months

1. Late breaking Science ESC CONGRESS 2017 TIDES-ACS Trial.
Reduced incidence of cardiac death and MI with OPTiMAX™ vs. SYNERGY™

MACE event rates and Definite or Probable ST at 12 months

When you look at the individual components of the primary endpoint in this study, the OPTiMAX™ stent comes with a lower rate of cardiac death and myocardial infarction compared to SYNERGY™, which is outbalanced by a higher rate of ischemia-driven target lesion revascularisation for OPTiMAX™. In other words, with the OPTiMAX™ stent hard clinical endpoints like myocardial infarction and cardiac death are less frequent in ACS patients than with SYNERGY™, at the cost of a, probably less important, higher rate of repeat intervention.” announced Dr. Pim Tonino. (Heart center Catharina Hospital, Eindhoven, the Netherlands).

OPTiMAX™ demonstrated statistically significant safety advantages for patients with acute coronary syndrome

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1. Late breaking Science ESC CONGRESS 2017 TIDES-ACS Trial.
OPTiMAX™: demonstrated NON-INFERIORITY to 3\textsuperscript{rd} generation Drug-Eluting Stent\textsuperscript{1}

As EFFECTIVE with a stronger SAFETY profile\textsuperscript{1}

TIDES-ACS key results at 12 months:

- OPTiMAX™ stent met the primary endpoint of non-inferiority to SYNERGY™\textsuperscript{1}
- OPTiMAX™ demonstrated a reduced incidence of cardiac death, myocardial infarction, Definite or Probable ST with a significantly lower duration of DAPT (P=0.007) vs. SYNERGY™\textsuperscript{1}

OPTiMAX™ SURFACE NO STENT: Optimising Performance, Maximising Safety\textsuperscript{1}

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1. Late breaking Science ESC CONGRESS 2017 TIDES-ACS Trial.