SORT OUT X

Comparison of Combo Dual Therapy Sirolimus-eluting stent (DTS) to ultrathin strut **Orsiro®** Biodegradable Polymer Sirolimus-eluting stent (BP-SES) in an all-comers population

Conclusions

- Combo failed to show non-inferiority to Orsiro with respect to Target Lesion Failure (TLF) at 12 months (6.3% vs. 3.7%, p = 0.00086).
- Target Lesion Revascularization (TLR) rate for Combo was significantly higher compared to Orsiro (3.4% vs. 1.5%, p = 0.0012).
- Rates of Target Vessel Revascularization (TVR) and patient related endpoints were significantly higher in the Combo arm.

Study design

Large scale, all-comers, multicentre, single-blind, two-arm, 1:1 randomized, non-inferiority trial comparing Combo to Orsiro stent in patients undergoing PCI.

Endpoints

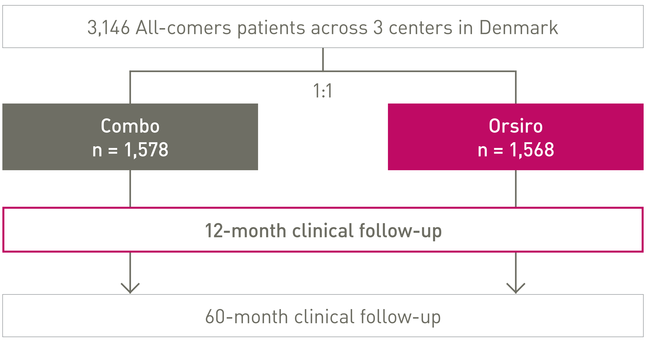
Primary endpoint

Target Lesion Failure (TLF) at 12 months, defined as the composite of:

- Cardiac Death
- Target vessel Myocardial Infarction (TV-MI)
- Target Lesion Revascularization (TLR)

Secondary endpoints

- Individual components of the primary endpoint
- All-cause death
- Target Vessel Revascularization (TVR)
- Stent Thrombosis (ST) (all, definite, definite/probable, probable, possible ST)
- Patient related endpoint (death, MI or any revascularization)

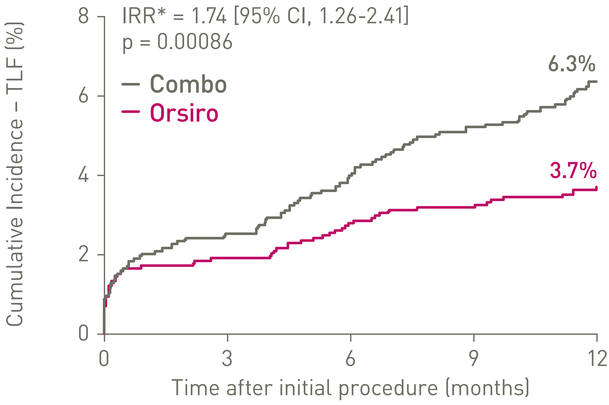


Patient characteristics[1]	Combo n = 1,578	Orsiro n = 1,568
Age (years)*	67.1 ± 10.7	66.7 ± 10.9
Male	76.9%	77.0%
Smoker	29.1%	30.5%
Diabetes mellitus	17.7%	17.3%
Hypertention	53.7%	56.6%
Hypercholesterolemia	50.3%	50.7%
Previous MI	15.4%	14.5%
Previous PCI	18.9%	19.7%
Previous CABG	7.1%	5.8%
Clinical indication		
STEMI	24.7%	22.6%
NSTEMI or Unstable Angina	29.6%	31.8%
Stable Angina	41.3%	41.7%

Lesion and Procedural characteristics[1]	Combo n = 2,008	Orsiro n = 1,982
Number of target lesions/patient		
1	74.3%	74.9%
2	20.3%	19.9%
3	4.4%	3.6%
Lesion Type		
B2	21.5%	20.3%
C	41.1%	39.5%
Bifurcation lesions	24%	22.8%
Chronic Total Occlusion	4.4%	5.2%
Lesion Length (mm)*	22.8 ± 15.6	22.8 ± 15.8
Reference vessel diameter (mm)*	3.4 ± 0.6	3.4 ± 0.6
Number of stents/patient*	1.7 ± 1.0	1.7 ± 1.1
Total stent length (mm)*	28.1 ± 18.0	28.3 ± 18.2

* Data shown as mean ± SD

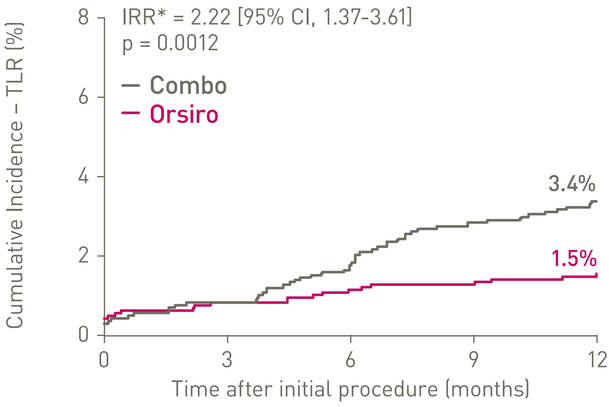
TLF at 12 months[1]



Combo is inferior to **Orsiro** with respect to TLF at 12 months

* Incidence rate ratios

TLR at 12 months[1]



Significantly lower TLR rate for **Orsiro** compared to Combo

Selected secondary endpoints at 12 months[1]

	Combo n = 1,578	Orsiro n = 1,568	p-value
Cardiac Death	1.6%	1.5%	0.78
TV-MI	2.7%	1.8%	0.10
TLR	3.4%	1.5%	**0.0012**
TVR	5.1%	2.8%	**0.0013**
Definite ST	0.5%	0.4%	0.60
Definite/probable ST	0.6%	0.4%	0.47
Patient related endpoint	14.9%	11.9%	**0.015**

Subgroup analysis – TLF at 12 months[1]

		Combo	Orsiro	Rate Ratio (95% BCI**)	Favors Combo / Favors Orsiro	p for interaction
ACS	no	43 (6.0%)	23 (3.2%)	1.88 (1.13-3.14)		0.69
	yes	57 (6.7%)	35 (4.1%)	1.65 (1.08-2.52)		
Diabetes mellitus	no	74 (5.7%)	45 (3.5%)	1.67 (1.15-2.42)		0.65
	yes	26 (9.3%)	13 (4.8%)	1.99 (1.02-3.90)		
Lesion Type C	no	48 (6.7%)	37 (5.3%)	1.29 (0.83-1.98)		0.044
	yes	52 (6.0%)	21 (2.4%)	2.54 (1.52-4.22)		
MVD	no	75 (5.9%)	45 (3.5%)	1.69 (1.17-2.45)		0.78
	yes	25 (8.2%)	13 (4.5%)	1.90 (0.96-3.77)		
STEMI	no	82 (6.9%)	48 (4.0%)	1.77 (1.24-2.54)		0.88
	yes	18 (4.6%)	10 (2.8%)	1.66 (0.76-3.62)		

Principal investigator

Lars Jakobsen, Aarhus University Hospital Skejby, Denmark

1. Jakobsen L et al. Randomized clinical comparison of the dual therapy CD34 antibody-covered sirolimus-eluting combo stent with the sirolimus-eluting orsiro stent in patients treated with percutaneous coronary intervention. The SORT OUT X trial. Circulation (2021).

Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes. Orsiro and Orsiro Mission are trademarks or registered trademarks of the BIOTRONIK Group of Companies.

Jun_2021

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach,
Switzerland

Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

BIOTRONIK
excellence for life