

NOBORI 1

Long Term Results:
Two Years Phase 1 & 2
Three Years Phase 1

Study Design

363 patients
29 sites
2:1 randomization
Single blind - two vessel – staging allowed

Up to two lesions in two coronary arteries
Vessel diameter: 2.5-3.5 mm
Lesion length: <25 mm
Predilatation required

Baseline Demographics

Patient characteristic	Nobori® Arm N=238	Taxus™ Arm N=125	P-value
Age (years)	63.2±10.6	62.9±10.0	0.78
Sex: male	72.7 (173/238)	68.0 (85/125)	0.39
Previous MI	23.5 (56/238)	28.0 (35/125)	0.37
Previous PTCA/CABG	24.7 (56/238)	20.6 (4/125)	0.67
Diabetes mellitus	16.8 (40/238)	27.2 (34/125)	0.03
insulin dependent	7.6 (18/238)	3.2 (4/125)	
non insulin dependent	9.2 (22/238)	24.0 (30/125)	
Hypertension	65.6 (156/238)	68.0 (85/125)	0.73
Hypercholesterolemia	69.8 (166/238)	74.4 (93/125)	0.39
Smoking history	59.5 (141/238)	52.8 (66/125)	0.22
Stable angina	71.8 (148/206)	71.6 (83/116)	0.96
Unstable angina	28.2 (58/206)	28.4 (33/116)	

NOBORI 1 met the primary endpoint

- Delta non-inferiority margin: 0.20mm
- In stent late loss results at 9 months
0.32 ± 0.50 mm Taxus™
0.11 ± 0.30 mm Nobori®

Nobori® = NON-INFERIOR p<0.001
Nobori® = SUPERIOR p=0.001

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Excellent results in NOBORI 1 Pooled data Phase 1 & 2 up to 2 Years

All Events	Nobori® Arm N=238	Taxus™ Arm N=125
Cardiac Death (% and N/Total)	1.7 (4/238)	0.8 (1/125)
MI - Total	5.0 (12/238)	7.2 (9/125)
MI Q Wave	0.4 (1/238)	4.0 (5/125)
MI Non-Q Wave	4.6 (11/238)	3.2 (4/125)
Emergent CABG	0.0 (0/238)	0.8 (1/125)
TL Re-PCI-Clinically driven	0.8 (2/238)	1.6 (2/125)
TV Re-PCI, non TL-Clinically driven	2.1 (5/238)	2.4 (2/125)
MACE Rate (%)	8.0	8.8
Target Vessel Failure (%)	7.6	8.0

No Stent Thrombosis up to 3 years in Nobori® Arm

Stent Thrombosis per Protocol

	Nobori® Stent N=235	Taxus™ Stent N=125
Acute	0.0	2.4
Sub-acute	0.0	1.6
Late	0.0	1.6
Total up to 2 years	0.0	4.0
Total up to 3 years**	0.0	4.8

Stent Thrombosis According to ARC*

	Nobori® Stent N=235	Taxus™ Stent N=125
Early	0.0	1.6
Late	0.0	0.0
Very late	0.0	1.6
Definite and probable	0.0	3.2
Total up to 3 years**	0.0	3.2

Dual Antiplatelet Therapy

Two Years	Three Years
Nobori® = 32%	Nobori® = 22%
Taxus™ = 34%	Taxus™ = 15%

MACE = Cradiac death, MI, clinically driven TVR – hierarchical events
TVF: cardiac death MI - TV related, CDTVR: hierarchical events
*ARC = Academic Research Consortium - Definite and probable
**Only patients from Phase 1 were followed up to 3 Years