

PRISM (Basket of Clinical Trial): Prospective Non-Randomized Studies to Investigate Safety and Efficacy of M'Sure-S (Sirolimus Eluting Coronary Stent). EURO-PRISM PRISM- INDIAN SUBCONTINENT PRISM-PILOT

Control Number:

5232

Submission Type:

LBCT or First Report Investigation

New Device/Innovation:

No

Author(s):

Marc silvestri¹

Institution(s):

¹Clinique Axiom, marseille, france

Trial Description:

PRISM Basket of Clinical Trial has been initiated to prove that In spite of availability of next generation limus analogues still Sirolimus Eluting Coronary stent is the most analysed & ideal Gold standard choice to treat the obstructive coronary artery diseases. In this study we have proved the continued safety and efficacy of M'Sure-S sirolimus eluting coronary stent in the treatment of obstructive coronary artery diseases.

PRISM-PILOT:

The PRISM Pilot is a prospective, single-centre, non-randomized Study to Investigate the safety and efficacy of M'Sure-S in 32 patients with a single de novo lesion in native coronary arteries. The primary safety and efficacy end-points were major adverse cardiac events (MACE) at 30 days and in-stent late lumen loss at six months, measured using QCA.

EURO -PRISM:

The EURO-PRISM is a Single centre, prospective Registry aimed at evaluating the Clinical safety of the M'Sure-S Sirolimus eluting stent in reducing neointimal hyperplasia and decreasing restenosis during PCI of stenotic coronary artery disease as well as intermediate term outcomes. 100 patients have been enrolled in the Registry.

Objectives

The main objective of this Registry is to assess the safety and Clinical performance of the M'Sure S Sirolimus eluting stent in obstructive Coronary Artery Disease.

PRISM-INDIAN SUBCONTINENT:

The PRISM-INDIAN SUBCONTINENT is a multi centre, prospective Registry aimed at evaluating the safety and effectiveness of the M'Sure S Sirolimus eluting stent in reducing neointimal hyperplasia and decreasing restenosis during PCI of stenotic coronary artery disease as well as intermediate term outcomes. Approximately 100 patients will be recruited in the study.

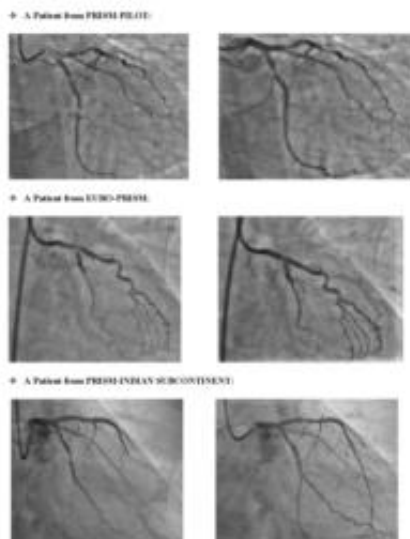
Objectives:

The main objective of this Registry is to assess the safety and effectiveness of the M'Sure S Sirolimus eluting stent in obstructive Coronary Artery Disease.

Supporting File(s)

Baseline Demographics PRISM INDIAN SUBCONTINENT EURO PRISM PRISM PILOT Total Number of patients enrolled 36 99 32 167 Mean age, years 57.6 ± 9.2 68 57.5 ± 9.7 61±9.4 Gender: Male 32 (88.89 %) NOT AVAILABLE 30(93.7%) 62(91.29%) Female 04 (11.11) NOT AVAILABLE 2 (6.3%) 06 (19.62%) Hypertension 17(47.22 %) NOT AVAILABLE 16 (50%) 33 (48.61%) Heart rate (beats per minute) 74.0 ± 21.48 NOT AVAILABLE 83.25 ± 14.8 78.62 ± 18.14 Previous myocardial infarction 04 (11.11 %) NOT AVAILABLE 09 (28.13%) 13 (19.62%) Anginal status stable angina 16 (44.44 %) 50 (50%) 06 (18.75%) 72 (37.73%) Acute Coronary Syndrome (ACS) 20 (55.55%) 30 (30 %) 26 (81.25%) 76 (43.75%) Diabetes 14

(38.88 %) 30 (30%) 07 (21.88%) 51 (25.29%) Smoker 11 (30.55 %) NOT AVAILABLE 22 (68.75%) 33 (49.65%)
 Hyperlipidemia 00 (0 %) NOT AVAILABLE 08 (25%) 8 (12.5%) Family history of coronary artery disease 05 (13.88%) NOT
 AVAILABLE 14 (43.75%) 19 (28.81%) Baseline Treatment Details Baseline Demographics PRISM INDIAN SUBCONTINENT
 EURO PRISM PRISM PILOT TOTAL Number of patients treated 36 99 32 167 Number of M'Sure-S Stents used 43 159 33
 235 Number of Diseased Coronary Arteries Single-vessel disease 30 (83.33%) 44 (44.44 %) 27 (84.38%) 100 (59.88%)
 Two-vessel disease 06 (16.67 %) 32 (32.32 %) 05 (15.63%) 43 (25.74%) Triple vessel disease 0 23 (23.23 %) 0 23
 (13.77%) Thrombolysis in Myocardial Infarction Flow Pre-procedure TIMI flow 0 02 (5.55%) 05 (13.89 %) 06 (18.75%) 13
 (7.78 %) TIMI flow I 16 (44.44%) 01 (1.01%) 15 (46.88%) 32 (19.16 %) TIMI flow II 03 (8.33%) 02 (2.02%) 11 (34.38%) 16
 (9.58 %) TIMI flow III 13 (36.11%) 91 (91.91 %) 00 (0.00%) 104 (62.27 %) Lesion Site Location Right coronary artery 13
 (36.11%) 43 (43.43%) 08 (25%) 64 (38.32%) Left anterior descending artery 16 (44.44%) 60 (60.60 %) 16 (50%) 92
 (55.08%) Left circumflex artery 06 (16.67 %) 23 (23.23 %) 05 (15.63%) 34 (20.35%) Obtuse marginal artery 01 (2.77 %) 05
 (5.05 %) 01 (3.13%) 08 (4.79%) Left Main 00 (0.00%) 03 (3.03 %) 00 (0.00%) 03 (1.79%) SVG 00 (0.00%) 02 (2.02 %) 00
 (0.00%) 02 (1.19%) M'Sure-S Stent Deployment Details Average stented diameter (mm) 2.93 ± 0.60 2.93 ± 0.60 2.93 ± 0.30
 2.93 ± 0.50 Average stented length (mm) 26.0 ± 9.79 24.0 ± 10.95 20.12 ± 4.56 23.0 ± 8.00 Stent Diameters (mm) 2.5 05
 (13.89 %) 28 (28.28 %) 04 (12.12%) 37 (15.74%) 2.75 09 (25.0 %) 44 (44.44 %) 12 (36.36%) 65 (27.65%) 3 15 (41.66 %) 41
 (41.41 %) 12 (36.36%) 68 (28.93%) 3.5 13 (36.11%) 31 (31.31%) 05 (15.15%) 49 (20.85%) 4 01 (2.77%) 16 (16.16 %) 00
 (0%) 17 (7.23%) Stent Lengths (mm) 8 00 (0%) 11 (11.11 %) 00 (0%) 11 (4.68%) 12 01 (2.77%) 12 (12.12 %) 02 (6.06%) 15
 (6.38%) 16 10 (27.27%) 27 (27.27 %) 09 (27.27%) 46 (19.57%) 20 15 (41.66 %) 29 (29.29 %) 11 (33.33%) 55 (23.4%) 24 07
 (19.44%) 22 (22.22 %) 08 (24.24%) 37 (15.74%) 28 04 (11.11%) 19 (19.19 %) 02 (6.06%) 25 (10.64%) 32 01 (2.77%) 12
 (12.12%) 01 (3.03%) 14 (5.95%) 36 02 (5.55 %) 08 (8.08%) 00 (0%) 10 (4.25%) 40 03 (8.33%) 20 (20.20%) 00 (0%) 23
 (9.78%) Post-Procedure and Discharge Details Baseline Demographics Details Number of patients 36 99 32 167 Adverse
 events 00 (0%) 00 (0%) 00 (0%) 00 (0%) Serious adverse events 00 (0%) 02 (2.02 0%) 00 (0%) 02 (2.02 0%) Unanticipated
 device-related events 00 (0%) 00 (0%) 00 (0%) 00 (0%) Instances of device malfunction 00 (0%) 00 (0%) 00 (0%) 00 (0%)
 Post-procedure Discharge Details Death 00 (0%) 00 (0%) 00 (0%) 00 (0%) Cardiac death 00 (0%) 00 (0%) 00 (0%) 00 (0%)
 Non-cardiac death 00 (0%) 00 (0%) 00 (0%) 00 (0%) Myocardial infarction 00 (0%) 02 (2.02 %) 00 (0%) 02 (2.02 %) Q-wave
 myocardial infarction 00 (0%) 00 (0%) 00 (0%) 00 (0%) Non-Q-wave myocardial infarction 00 (0%) 00 (0%) 00 (0%) 00 (0%)
 Target lesion revascularization 00 (0%) 00 (0%) 00 (0%) 00 (0%) Repeat Percutaneous coronary intervention 00 (0%) 00
 (0%) 00 (0%) 00 (0%) Coronary artery bypass graft surgery 00 (0%) 00 (0%) 00 (0%) 00 (0%) Target vessel
 revascularization 00 (0%) 00 (0%) 00 (0%) 00 (0%) Any other complication 00 (0%) 00 (0%) 00 (0%) 00 (0%) ASSESSMENT
 OF 1 MONTH DATA PRISM - PILOT PRISM INDIAN SUBCONTINENT EURO PRISM Total No. of patient completed the follow
 up 32 36 80 148 Adverse events 0 0 0 0 Serious adverse events 0 0 2 2 Death 0 0 0 0 Myocardial infarction 0 0 0 0 Target
 lesion revascularization 0 0 0 0 Repeat Percutaneous coronary intervention 0 0 0 0 Coronary artery bypass graft surgery 0 0
 0 0 Target vessel revascularization 0 0 0 0 ASSESSMENT OF 6 MONTH DATA No. of patient completed the follow up 27 36
 NA 63 Adverse events 0 0 0 0 Serious adverse events 0 0 0 0 Death 0 0 0 0 Myocardial infarction 0 0 0 0 Target lesion
 revascularization 0 0 0 0 Repeat Percutaneous coronary intervention 0 0 0 0 Coronary artery bypass graft surgery 0 0 0 0 Target
 vessel revascularization 0 0 0 6 MONTH QCA RESULTS 0.05 MM LATE LOSS NA NA



Category of Submission

First Report Investigation = smaller randomized trial, novel science or early human investigation

Trial Design

Prospective

Meta-Analysis, Randomized, Registry, etc.

Registry/Observational

Double-blind, Single-blind, Unblinded

Unblinded

Placebo Controlled, Active Controlled, Non-controlled

Active control

Quality Control

Independent on-site monitoring

Independent clinical events committee

Independent core laboratories (specify for which endpoints below)

Patients:

232

Clinical Sites:

05

List all pre-specified primary endpoint(s) (and follow-up duration), regardless of whether the endpoint(s) will be presented at TCT:

PRISM-PILOT: The primary safety and efficacy end-points were major adverse cardiac events (MACE) at 30 days and in-stent late lumen loss at six months, measured using QCA.

EURO -PRISM: The primary objective of this Registry is to study the difference in MACE rate at 30 days. Defined as a composite of Death, MI (both Q-wave and Non Q-wave MI), Emergent CABG, or clinically driven TLR (repeat PCI or CABG).

PRISM-INDIAN SUBCONTINENT: The primary objective of this Registry is to study the difference

Will the primary endpoint(s) be presented for the first time ever at TCT 2014?

Yes

List all secondary endpoints (and follow-up duration) that will be presented for the first time ever at TCT 2013. If no secondary endpoints are to be presented, enter None.

NONE

Funding Sources

Multimedics