Boston Scientific

PCI Investigator-Sponsored Research[1]

RECHARGE ▪ Registry of CrossBoss and Hybrid Procedures

Enrollment Complete
Sept 2015
100% F/U Visits Complete
Dec 2016

1200 patients

France, Netherlands, Belgium, United Kingdom

Clinical validation of efficacy & efficiency of the Hybrid Algorithm & the use of CrossBoss™ and Stingray™ technologies.

Principal Investigator: Prof. Dr. Jo Dens

OPEN CTO ▪ Outcomes, Patient Health Status, and Efficiency in CTOs

Enrollment Complete
July 2015
12 Month F/U Complete
Sept 2016

N=1000 coronary CTO procedures

Safety & Effectiveness of Hybrid Algorithm & CrossBoss and Stingray Technologies

Principal Investigator: J. Aaron Grantham, MD

CrossBoss First ▪ Randomized Comparison of CrossBoss First vs. Standard Wire Escalation for Crossing CTOs

Now Enrolling
(50% Dec 2016)

n=246 patients

Efficacy objective: compare procedure time required to cross CTO or abort procedure with CrossBoss first vs. antegrade wire escalation. Safety objective: compare frequency of procedural MACE with upfront use of CrossBoss vs. guidewire escalation.

Principal Investigator: Emmanouil Brilakis, MD

CONSISTENT CTO ▪ Safety And Efficacy of Sub-Intimal Stenting with SYNERGY in CTO

Now Enrolling

200 patients

Primary Endpoint

6 sites

Prospective, multi-center, single arm

Principal Investigator: Simon Walsh, MD

OPTIMUM ▪ A Prospective Registry

Now Enrolling
up to 800

Planning to enroll 800

Mulit-Centre, Observational registry study

Outcomes of Percutaneous Revascularization or Medical Therapy for Surgically Ineligible Patients with Multivessel or Left Main Coronary Artery Disease

Principal Investigator: J. Aaron Grantham, MD

SYNTAX II ▪ Multi-Vessel Disease

Enrollment Complete

400 patients

Primary Endpoint

SYNERGY Stent single arm, compared to historical CABG population; IVUS and FFR to be utilized

Principal Investigator: Javier Escaned, MD

IDEAL LM ▪ Left Main European RCT

Now Enrolling

818 patients

Primary Endpoints

20 sites

SYNERGY Stent vs. Xience™ Stent, (RCT 1:1); OCT healing substudy at 3-months

Principal Investigator: Robert-Jan van Geuns, MD

CELTIC BIFURCATION ▪ Coronary Bifurcation Study (Culottes Bifurcation Stenting)

Now Enrolling

170 patients

Primary Endpoint

9 sites

SYNERGY Stent vs. Xience Xpedition™ Stent (RCT 1:1)

Principal Investigator: David Foley, MD

SENIOR ▪ Reduced DAPT in Elderly

Now Enrolling

~1200 patients

40 sites

SYNERGY Stent vs. BMS 1-month DAPT in elective patients and 6-months DAPT in ACS patients (RCT 1:1)

Principal Investigator: Olivier Varenne MD, PhD

BIORESORT ▪ All Comers with Diabetes Substudy

Enrollment Complete

3450 patients

Primary Endpoint

SYNERGY Stent vs. Resolute Integrity™ Stent vs. Orsiro™ Stent (RCT 1:1:1)

Principal Investigator: Clemens von Birgelen, MD, PhD

1. Boston Scientific is not responsible for the collection, analysis or reporting of the investigator-sponsored research output which is the sole responsibility of the investigators. Boston Scientific's involvement in investigator-sponsored research is limited to providing financial support for research that advances medical and scientific knowledge about our products. Safety and performance of the SYNERGY Coronary Stent System has not been established for use in patients with STEMI, Left Main, chronic total occlusion, bifurcation and multi-vessel disease stenting. The SYNERGY Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de novo native coronary artery lesions.
2. For the SYNTAX II study, MACCE is defined as: all-cause death; cerebrovascular event (stroke); documented myocardial infarction or all-cause revascularization.
3. For the CELTIC BIRFUCATION Study Clinical and Angiographic composite is defined as: Death, Myocardial Infarction, CVA (cerebrovascular events), Target Vessel Failure (Composite of Target Vessel Revascularization and Target Vessel Inadequacy); Definite or Probable stent thrombosis (ARC criteria); Binary angiographic restenosis.
4. For the IDEAL-LM study, MACCE is defined as: all-cause death; stroke; myocardial infarction or ischemia driven target vessel revascularization.
5. Target Vessel Failure is defined as any ischemia-driven revascularization of the target vessel, MI (Q-wave and non–Q-wave) related to the target vessel or cardiac death.