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017 (1) THE SYNERGY BETWEEN PERCUTANEOUS CORONARY INTERVENTION AND CARDIAC SURGERY (SYNTAX) STUDY: THE DESIGN AND RATIONALE OF A COMPREHENSIVE STUDY COMPARING PERCUTANEOUS CORONARY INTERVENTION USING TAXUS DRUG-ELUTING STENT WITH CORONARY ARTERY BYPASS GRAFT TREATMENT IN PATIENTS REQUIRING REVASCULARISATION FOR DE NOVO THREE-VESSEL DISEASE AND/OR LEFT MAIN DISEASE

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Objectives: Percutaneous coronary intervention (PCI) with drug-eluting stents is challenging coronary artery bypass surgery (CABG) as the gold standard for treatment of three-vessel (3VD) and/or left main (LM) coronary disease. SYNTAX is a novel trial comparing PCI with paclitaxel-eluting TAXUS stents to CABG for 3VD and LM patients. The design and rationale of SYNTAX will be described and final enrollment numbers will be reported.

Methods: In the SYNTAX trial, investigators at 85 sites (62 European/23 U.S.) collected safety and outcomes data for patients with de novo 3VD and/or LM disease treated by PCI with TAXUS stents or CABG. A Heart Consultation Team (surgeon and interventionalist) determined the eligibility of all consecutive patients for each revascularisation treatment option. If suitable for both options, patients were randomised to TAXUS or CABG (stratified by LM disease and diabetes) and if suitable for only one treatment option, they were entered into a nested registry. A SYNTAX score was calculated to quantify the complexity of coronary artery disease by taking into account the number and location as well as the complexity of each lesion independently. For the primary randomised controlled trial endpoint of 12-month MACCE (major adverse cardiac and cerebral events), a non-inferiority comparison will be performed. Specifically, if the upper one-sided 95% confidence bound for the difference in 12-month MACCE rates (test minus control) is less than a delta of 6.6% (at a 5% significance level), PCI with TAXUS will be considered to be non-inferior to CABG in the population of patients being analysed.

Results: Trial enrollment is complete with 1800 patients in the RCT (1090 3VD and 710 LM). In addition, 198 patients were enrolled in the PCI registry (60% LM and 40% 3VD) and 1077 in the CABG registry (52% 3VD and 48% LM).

Conclusions: SYNTAX is a novel trial that will provide evidence-based medicine to determine the optimal revascularisation method, PCI or CABG, for patients with de novo 3 VD and/or LM disease.

017 (2) PRIMARY ENDPOINT OF THE SYNERGY BETWEEN PERCUTANEOUS CORONARY INTERVENTION AND CARDIAC SURGERY (SYNTAX) STUDY: A COMPREHENSIVE STUDY COMPARING PERCUTANEOUS CORONARY INTERVENTION (PCI), USING TAXUS EXPRESS2 PACLITAXEL-ELUTING STENT, WITH CORONARY ARTERY BYPASS GRAFT (CABG) TREATMENT IN PATIENTS REQUIRING REVASCULARISATION FOR DE NOVO THREE-VESSEL DISEASE (3VD) AND/OR LEFT MAIN (LM) DISEASE

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Objectives: The SYNTAX trial was designed to compare percutaneous coronary intervention (PCI) with TAXUS stents versus coronary artery bypass surgery (CABG) for the treatment of de novo three-vessel (3VD) and/or left main coronary disease (LM).

Methods: SYNTAX is a prospective, multicentre, multinational, randomised clinical trial (RCT) with nested registries. Consecutive patients with de novo 3VD or LM disease were screened by a Heart Consultation Team (surgeon and interventionalist) to determine eligibility for PCI or CABG. If amenable for both, they were randomised to TAXUS or CABG, stratified at each site by LM disease and diabetes. If a patient was suitable for only one treatment option, they were entered into the PCI registry for CABG-ineligible patients or CABG registry for PCI-ineligible patients.

Results: A total of 1800 patients were randomised (1090 3VD and 710 LM) at 85 sites. Additionally, 198 patients were enrolled in the PCI registry and 1077 in the CABG registry. The TAXUS and CABG groups in the RCT were well-matched for baseline characteristics. The primary endpoint of SYNTAX, 12-month MACCE (major adverse cardiac and cerebrovascular events, defined as all-cause death, stroke, MI, or repeat vascularisation), and outcomes of the nested registries will be available at the time of the presentation.

Conclusions: SYNTAX is a novel trial that will provide evidence-based medicine to determine the optimal revascularisation method, PCI or CABG, for patients with de novo 3 VD and/or LM disease, while defining the patient populations that are amenable for only one of these treatment options.