



PEPCAD III – Paclitaxel-Eluting PTCA-Balloon in Combination With the Coroflex™ Blue Stent vs. the Sirolimus Coated Cypher™ Stent in the Treatment of Advanced Coronary Artery Disease

B. Braun Melsungen AG, Vascular Systems, Clinical Science

Objective: The aim of the study is to assess the safety and efficacy of the Paclitaxel-eluting SeQuent Please S stent system (Coroflex DEBlue) in the treatment of stenoses in native coronary arteries with nominal stent diameters between ≥ 2.5 mm and ≤ 3.5 mm and < 24 mm in length for procedural success and preservation of vessel patency in comparison to the Sirolimus-eluting Cypher™ stent.

Study Design: This study is a prospective, randomized, multi-center, two-armed phase-II study conducted in Europe.

Number of patients: 600 patients will be randomly assigned to either one of the treatment groups in the order of 20 to 40 patients per centre and a minimum of 10 procedures per operator.

Selection Criteria: Patients with stable or selected forms of unstable angina or documented ischemia due to a significant lesion in a native coronary artery. Vessels may not supply an entirely infarcted myocardial area.

Primary Variable: Late lumen loss at 9 months. A deviation of +/- 3 months to the 9 months FU is accepted.

Secondary Variables: Procedural success; 30-day complication rate (by phone); Percent stenosis at 9 months; Angiographic binary restenosis rate at 9 months; Acute and cumulative MACE rate at 9 months; Cumulative MACE rate after one year; Cumulative MACE rate after three years; Indication for premature follow-up

Scheduled Follow-up: Clinical and angiographic follow-up scheduled at 9 months for all patients; 1 and 3 year MACE for all patients

Principle investigators: Prof. C. Hamm, Kerckhoff - Clinic Bad Nauheim, Germany
Prof. B. Scheller, University of Saarland - Internal Medicine III, Homburg/Saar, Germany

Status: Recruitment finalized, Follow-ups in progress

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Register: <http://clinicaltrials.gov/ct2/show/NCT00473772>