



PEPCAD V – Paclitaxel-Eluting Balloon Angioplasty and Coroflex™-Stents in the Treatment of Bifurcated Coronary Lesions

B. Braun Melsungen AG, Vascular Systems, Clinical Science

Objective: The aim of the study is to investigate the feasibility of Paclitaxel-eluting PTCA-balloon dilation (SeQuent™ Please) followed by bare metal stent (Coroflex™) deployment in the main branch (reference diameter: ≥ 2.5 mm and ≤ 3.8 mm, reference diameter of side branch:

≥ 2.0 mm and ≤ 3.5 mm, length of stenoses in either branch ≤ 20 mm) in the treatment of significant ($>70\%$) de-novo-bifurcation stenoses of any Medina classification type in the native left coronary artery as reflected by procedural success and to evaluate the preservation of vessel patency.

Study Design: This study is a prospective, dual-center, single arm phase-II feasibility pilot study conducted in Germany.

Number of patients: 25 patients with bifurcational coronary artery lesions shall complete the study per protocol on the order of 10 to 15 patients per center.

Selection Criteria: Patients with stable or selected forms of unstable angina or documented ischemia due to a de-novo bifurcation stenosis of any Medina classification type in the left native coronary artery will be enrolled. Vessels may not supply an entirely infarcted myocardial area.

Primary Variable: Procedural success (main branch $\leq 30\%$, side branch $\leq 50\%$, TIMI Flow 3)

Secondary Variables: In-segment late lumen loss at 9 months in either branch; Occurrence of acute (≤ 24 hours), subacute (≤ 30 days), and late (≥ 30 days) thrombosis; 30-day MACE rate; Percent in-stent and in-segment stenosis at 9 months in either branch; In-stent and in-segment late loss and late loss index at 9 months in either branch; Angiographic binary in-stent and in-segment stenosis rate at 9 months in either branch; Acute and cumulative MACE rate at 9 months; Cumulative MACE rate after 3 years; Indication for premature follow-up; Type of recurrence (Mehran-Classification); Target vessel failure

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

Principle investigator: Prof. D.G. Mathey, University Cardiovascular Center Hamburg, Germany

Status: Recruitment finalized, Follow-up

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Register: <http://clinicaltrials.gov/ct2/show/NCT00540813>