



PEPCAD II – The Paclitaxel-Eluting PTCA-Balloon Catheter in Coronary Artery Disease to Treat In-Stent Restenoses: A Comparison to the Paclitaxel-Eluting Taxus™ Stent

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 PTCA-balloon in the treatment of in-stent restenoses in native coronary arteries with reference diameters between ≥ 2.5 mm and ≤ 3.5 mm and ≤ 22 mm in length for procedural success and preservation of vessel patency in comparison to the Paclitaxel-eluting Taxus™ stent.

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

Number of patients: 120 patients will be randomly assigned to either of the treatment groups in the order of 20 patients per center.

Selection Criteria: Patients with stable or selected forms of unstable angina or documented ischemia due to a first time in-stent restenosis in a native coronary artery will be enrolled. Vessels may not supply an entirely infarcted myocardial area.

Primary Variable: Late lumen loss at 6 months

Secondary Variables: Procedural success; Occurrence of acute (up to 48 hours), subacute (up to 30 days), and late thrombosis; 30-day MACE rate; Percent in-stent stenosis at 6 months; Percent in-segment stenosis at 6 months; In-stent late loss index at 6 months; Angiographic binary in-stent stenosis rate at 6 months; In-segment late loss index at 6 months; Angiographic binary in-segment stenosis rate at 6 months; Acute and cumulative MACE rate at 6 months; Cumulative MACE rate after one year; Cumulative MACE rate after three years; Indication for premature follow-up; Type of recurrence (Mehran-Classification); Target vessel failure

Scheduled Follow-up: Clinical and angiographic follow-up scheduled at 6 months and 1 and 3 year MACE for all patients

Principle investigator: Dr. M. Unverdorben, Clinical Research Institute - Center for Cardiovascular Diseases, Rotenburg a.d. Fulda, Germany

Status: Recruitment finalized, 1-year Follow-up

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Register: <http://clinicaltrials.gov/ct2/show/NCT00393315>