



PEPCAD I – The Paclitaxel–Eluting PTCA–Balloon Catheter to Treat Small Vessel Coronary Artery Disease

B. Braun Melsungen AG, Vascular Systems, Clinical Science

Objective: The objective of this study is to assess the safety and efficacy of the Paclitaxel-eluting PTCA-balloon catheter (3µg/mm² balloon surface area) in the treatment of significant ($\geq 70\%$ and $< 100\%$) stenoses in native coronary arteries with reference diameters from ≥ 2.25 mm to ≤ 2.8 mm and ≤ 22 mm in length for procedural success and preservation of vessel patency.

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

Number of patients: Eighty consecutive patients of either gender treated per protocol will be enrolled in the range of 20 patients per center.

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

Primary Variable: Angiographic late loss at 6 months

Secondary Variables: Procedural success; 30-day MACE rate; Percent stenosis at 6 months; Binary restenosis rate at 6 months; Late loss index at 6 months; Cumulative MACE rate at 6 months; Indication for premature follow-up; Cumulative MACE rate at 1 year; Cumulative MACE rate at 3 years

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

Publication: -

Sponsor: B. Braun Melsungen AG

Register: <http://clinicaltrials.gov/ct2/show/NCT00404144>