



PEPCAD-CTO – The Paclitaxel-Eluting PTCA-Balloon Catheter in Coronary Artery Disease to Treat Chronic Total Occlusions

B. Braun Melsungen AG, Vascular Systems, Clinical Science

Objective: The aim of the study is to assess the safety and efficacy of a Paclitaxel-eluting PTCA-balloon in combination with bare-metal stenting for treatment of chronic total occlusions in native coronary arteries with reference diameters between 2.5mm and 4.0mm.

Study Design: Treatment, Open Label, Historical Control, Single Group Assignment, Efficacy Study

Number of patients: 48 patients shall complete the study per protocol on the order of 25 patients per center.

Selection Criteria: Patients with chronic total occlusion, Thrombolysis in Myocardial Infarction (TIMI) flow 0 or 1, occlusion in native coronary artery, indication for percutaneous coronary intervention based on symptoms, prognosis or evidence of ischemia and reference diameter 2.5mm to 4.0mm will be enrolled.

Primary Variable: Late loss (Time Frame: 6 months)

Secondary Variables: percent diameter stenosis (Time Frame: 6 months); binary angiographic restenosis rate (Time Frame: 6 months); late loss index (Time Frame: 6 months); Target lumen revascularization (Time Frame: 30 days, 6, 12, 24 months); target vessel revascularization (Time Frame: 30 days, 6, 12, 24 months); major adverse cardiac events (Time Frame: 30 days, 6, 12, 24 months]

Scheduled Follow-up: see above

Principle investigator: Prof. Jochen Wöhrle, University of Ulm, Germany

Status: Recruiting

Publication: -

Sponsor: Investigator Initiated Trail

Register: <http://clinicaltrials.gov/ct2/show/NCT00670436>