



INDICOR – The Paclitaxel-Eluting PTCA-Balloon Catheter in Combination With a Cobalt-Chromium Stent to Treat Coronary Artery Disease in a Real World Scenario

B. Braun Melsungen AG, Vascular Systems, Clinical Science

Objective: The aim of the study is to evaluate the efficacy and safety of cobalt-chromium stent (Coroflex™ Blue) deployment followed by Paclitaxel-eluting PTCA-balloon dilatation (SeQuent™ Please) and of Paclitaxel-eluting PTCA-balloon dilatation (SeQuent™ Please) followed by cobalt-chromium stent (Coroflex™ Blue) deployment in a real world scenario including up to two de-novo or restenotic lesions (no in-stent restenoses) in two different native coronary arteries (reference diameter: $\geq 2.5\text{mm}$ and $\leq 4.0\text{mm}$, length of stenosis $\geq 10\text{mm}$ and $\leq 25\text{mm}$) for procedural success and preservation of vessel patency up to 3 years.

Study Design: This study is a controlled, prospective, multicenter, randomized, two arm phase-II study conducted in India.

Number of patients: 125 consecutive patients of either gender treated per protocol will be enrolled with a minimum of 10 patients per center. No center shall enroll more than 30 patients.

Selection Criteria: Patients with stable or selected forms of unstable angina or documented ischemia due to de-novo or restenotic lesions in one or two native coronary arteries will be enrolled.

Primary Variable: Late lumen loss at 6 months in-segment and in-stent for each treated coronary stenosis

Secondary Variables: Procedural success; Occurrence of acute (up to 48 hours), subacute (up to 30 days) and late thrombosis; MACE rates at 30 days, 6 months, and 1 and 3 years; Percent in-segment and in-stent stenosis at 6 months; Angiographic binary in-segment and in-stent restenosis rate at 6 months; In-segment and in-stent late loss index at 6 months; Indication for premature follow-up (e.g., angina pectoris...); Type of recurrence (Mehran-Classification); Target vessel failure

Scheduled Follow-up: Clinical and angiographic follow-up scheduled at 6 months, clinical follow-up only after 1 and 3 years

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Status: Recruiting

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Register: <http://clinicaltrials.gov/ct2/show/NCT00747357>