Universität Basel

Research Project

Basel Stent Kosten Effektivitäts Trial - Drug Eluting Balloons vs. Drug Eluting Stents in Small Vessel Interventions (BASKET-SMALL 2): A prospective, randomized, controlled, open label, multicenter trial

Third-party funded project

Project title Basel Stent Kosten Effektivitäts Trial - Drug Eluting Balloons vs. Drug Eluting Stents in Small Vessel Interventions (BASKET-SMALL 2): A prospective, randomized, controlled, open label, multicenter trial
Principal Investigator(s) Jeger, Raban ;
Co-Investigator(s) Kaiser, Christoph A. ;
Organisation / Research unit
Bereich Medizinische Fächer (Klinik) / Kardiologie
Department
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Background: The Basel Stent Kosten Effektivitäts Trial (BASKET) tested the cost-effectiveness of drug-eluting stents (DES) against bare metal stents (BMS) in percutaneous coronary interventions (PCI) irrespective of the indication and showed that patients with interventions in bypass grafts and small native vessels, i.e., less than 3.0 mm, benefited most from DES, not only by reducing target vessel revascularization (TVR), but also rates of cardiac death and non-fatal myocardial infarction. Therefore, additional trials in large native vessels (BASKET-PROVE and BASKET-PROVE II), bypass grafts (BASKET-SAVAGE), and small native vessels (BASKET-SMALL) were initiated. The present trial is a follow-up study of BASKET-SMALL that tested two different DES, i.e., the first-generation TAXUSő stent, a paclitaxel-eluting stainless steel stent with a durable polymer, against the second-generation Endeavorő stent, a zotarolimus-eluting cobalt-chromium stent with a biocompatible polymer in terms of major adverse clinical events (cardiac death, non-fatal myocardial infarction) after 18 months. Follow-up will end in late 2011. Hypothesis: In a real-world population undergoing PCI for de-novo stenoses in small native vessels with a diameter of less than 3.0 mm, drug eluting balloons (DEB) are able to reduce clinical event rates compared with third-generation DES. Design: Prospective, randomized, controlled, open-label, multicenter non-inferiority trial. Concomitant registry of patients with suitable inclusion criteria but flow-limiting dissections (Thrombolysis In Myocardial Infarction [TIMI] flow less or equal 2) or residual stenoses more or equal 30% after initial balloon inflation (see below) Inclusion criteria: PCI of de-novo stenoses in vessels less than 3.0 mm in diameter without a flow-limiting dissection (TIMI flow less or equal 2) or a residual stenosis more or equal 30% with the need for stent implantation after initial balloon inflation. Main exclusion criteria: Instent-restenosis, concomitant PCI of larger vessels, oral anticoagulation, planned surgery in the following 12 months. Intervention: Randomization 1:1 for a third-generation DES (paclitaxel-eluting Taxus Elementő stent, Boston Scientific Corp, Natick MA) vs. DEB (paclitaxel-eluting SeQuentő Please balloon, B. Braun Melsungen AG, Berlin, Germany). Patients without exclusion criteria but flow-limiting dissections and residual stenoses more or equal 30% after the initial balloon inflation will receive the same DES as in the randomized trial and enter a prospective registry. Primary endpoint: Major adverse cardiac events (MACE), defined as cardiac death, myocardial infarction, and TVR after 12 months. Secondary endpoints:MACE after 24 and 36 months; single components of the primary endpoint, target lesion revascularization, stent thrombosis (possible, probable, definite), overall mortality, TIMI major bleeding, net clinical benefit endpoint (primary endpoint and TIMI

major bleeding), and cost-effectiveness after 12, 24, and 36 months. Sample size: This non-inferiority trial aims to enroll 649 patients to ensure 616 evaluable patients. Assuming a dissection/residual stenosis rate of 33% and a drop-out rate of 5%, a total of 969 patients will need to be consented.

Keywords Coronary artery disease, Drug-eluting balloon, Drug-eluting stent, Clinical research, Outcome, Long-term follow-up
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