Titel des Beitrags:
Rationale and design of a randomized, double-blind, placebo-controlled trial of 6 versus 12 months clopidogrel therapy after implantation of a drug-eluting stent: The Intracoronary Stenting and Antithrombotic Regimen: Safety And Efficacy of Six Months Dual Antiplatelet Therapy After Drug-Eluting Stenting (ISAR-SAFE)

Abstract:
BACKGROUND: Concern regarding the rate of delayed acute stent thrombosis associated with drug-eluting stent (DES) treatment has resulted in upward revision of the advised duration of dual antiplatelet therapy after DES implantation by both European and United States guideline writing committees. In fact, the corroboration of an increased rate of late thrombotic events remains outstanding, and these clinical practice guidelines are limited by an inadequate evidence base on which to ground their recommendations. HYPOTHESIS: We postulate that a 6-month duration of clopidogrel therapy after DES implantation is associated with a clinical outcome that is not inferior to that of a 12-month therapy. STUDY DESIGN: The Intracoronary Stenting and Antithrombotic Regimen: Safety And Efficacy of Six Months Dual Antiplatelet Therapy After Drug-Eluting Stenting (ISAR-SAFE) is a multinational, double-blind, placebo-controlled, randomized trial designed to examine the effects of a 6-month duration of clopidogrel therapy after DES implantation.
compared to that of 12 months. Patients on clopidogrel therapy at 6 months after DES implantation will be randomized in a 1:1 fashion to discontinuation of clopidogrel versus a further 6 months of treatment. The primary end point is a composite of death, myocardial infarction, stent thrombosis, stroke, or thrombolysis in myocardial infarction major bleeding. Clinical follow-up is scheduled at 9 months postrandomization (15 months postintervention). According to power calculations based on a noninferiority design, it is estimated that 6,000 patients are required to be enrolled. SUMMARY: There is clinical equipoise on the issue of optimal duration of dual antiplatelet treatment after percutaneous intervention with DES. The ISAR-SAFE trial aims to assess whether discontinuation of clopidogrel 6 months after DES implantation is noninferior to routine prolongation of such therapy out to 1 year.