



## Lecture Notes

### American College of Cardiology 60<sup>th</sup> Annual Scientific Session & i2 Summit

#### **A Prospective, Randomized, Investigation of a Novel Platinum Chromium Everolimus-Eluting Coronary Stent: The PLATINUM Trial**

Sponsor: Boston Scientific Corporation

Clinical Trial #: NCT00823212

#### **Background**

Randomized trials have demonstrated an excellent safety and efficacy profile for the cobalt chromium everolimus-eluting stent (CoCr-EES). The platinum chromium everolimus-eluting stent (PtCr-EES) uses the identical antiproliferative agent and polymer with a novel platinum chromium scaffold designed for enhanced deliverability, vessel conformability, side-branch access, radiopacity, radial strength, and fracture resistance.

#### **Objectives**

To evaluate clinical outcomes with the novel PtCr-EES compared with CoCr-EES in patients undergoing percutaneous coronary intervention (PCI); and to assess an EES system [PROMUS Element] for the treatment of up to 2 *de novo* coronary artery lesions.

#### **Study Design**

- Large-scale, prospective, single-blind, multicenter randomized trial

#### **Primary Endpoint**

- The 12-month rate of target lesion failure (TLF), the composite of target vessel-related cardiac death, target vessel-related myocardial infarction (MI), or ischemia-driven target lesion revascularization (TLR) in the per-protocol population

#### **Methods**

- A total of 1530 patients undergoing PCI of 1 or 2 *de novo* native lesions were randomized at 132 sites worldwide to CoCr-EES (n=762) or PtCr-EES (n=768)



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#### Results

- The 12-month rate of TLF in the per-protocol population occurred in 2.9% versus 3.4% of patients with CoCr-EES compared with PtCr-EES, respectively (difference: 0.5%; 95% CI, -1.3% to 2.3%; p(noninferiority)=0.001; p(superiority)=0.60)
- In the intention-to-treat population, there were no significant differences between CoCr-EES and PtCr-EES in the 12-month rates of TLF (3.2% vs 3.5%; p=0.72), cardiac death or MI (2.5% vs 2.0%; p=0.56), TLR (1.9% vs 1.9%; p=0.96), or Academic Research Consortium definite or probable stent thrombosis (0.4% vs 0.4%; p=1.00)

#### Conclusion

A novel PtCr-EES was noninferior to the predicate CoCr-EES for TLF, with nonsignificant differences in measures of safety and efficacy through a 12-month follow-up after PCI.

#### Further Reading

Stone G et al. *J Am Coll Cardiol* 2011.