Reviewer's report

Title: A randomized multi-center comparison of hybrid sirolimus-eluting stents implantation with bioresorbable polymer versus everolimus-eluting stents with durable polymer for the treatment of total coronary occlusions: Rationale and design of the PRImary Stenting of Occluded Native coronary arteries IV study (PRISON IV).

Version: 1 Date: 28 April 2012

Reviewer: Roxana Mehran

Reviewer's report:

Summary: This study aims to enroll 330 patients with CTO and randomize them to SES with a bioresorbable polymer vs. EES with a durable polymer in 8 high volume PCI centers. Only functionally significant CTOs of at least 2.25-4 mm diameter will be included after successful recanalization. Events will be independently adjudicated, and monitored by an independent data safety monitoring board. The primary outcome will be in-segment late luminal loss at 9-month angiographic follow-up and QCA. OCT is planned for the first 60 patients, and will be completed with the 9-month angiogram. Multiple secondary angiographic and clinical endpoints will be assessed, including MACE (MI, death, or clinically driven TLR) and stent thrombosis (ARC criteria), with annual follow-up up to 5 years.

Major Compulsory Revisions:
- More information on patient recruitment and referral is needed
- Please provide more details on the randomization process and allocation concealment. Will both stents have the same packaging?
- Please describe how the investigators will account for loss to follow-up and patients who drop-out in the statistical analysis
- Will the authors provide an intention-to-treat or per-protocol analysis? How will the authors manage cross-over?
- The authors describe an open-label design, whereby patients will receive antiplatelet regimen per each operator’s discretion. How will they minimize bias?
- Will the investigators capture other clinical endpoints, such as contrast volume, acute kidney injury, contrast-induced nephropathy, or major bleeding?

Minor Essential Revisions
- Please have the manuscript revised for grammatical and spelling errors

Discretionary Revisions
- A diagram would be helpful showing the process of recruitment, enrollment and randomization
**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

AstraZeneca, Consultant
Ortho McNeill-Janssen, Advisory Board
Regado, Advisory Board
BMS/Sanofi, Research Grant Support (institutional)
The Medicines Co., Research Grant Support (spouse)