Reviewer's report


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Reviewer: lawrence friedman

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In general, it is a well-written, clear summary of the protocol that contains the necessary items.

My major comments concern the sample size and analysis sections. Because this is a noninferiority trial, I think that more information about the selection of the margins would be helpful. Why was a noninferiority margin of 1.5 chosen? If the rate in the PtCr-ESS rate could be as high as 9.5% (or even more), is that not important? In superiority trials of cardiovascular disease, we are often happy if the new treatment is 20% or 30% better (relative benefit), yet here we would accept a 50% worsening as equivalent. A similar relative (though smaller absolute) difference seems to be used for the TAT/DDAT comparison. For the stent comparison, why was a 2:1 randomization ratio chosen? For both analyses, how will missing data be handled?

Two more minor comments:
i) Because of the many abbreviations and acronyms, it would help to have a table at the back of all of them.
ii) On page X, third line from the bottom: The middle “e” in “treatment” should be deleted.