Reviewer's report

Title: A novel endothelial damage inhibitor for the treatment of vascular conduits in coronary artery bypass grafting: protocol and rationale for the European, multicentre, prospective, observational DuraGraft registry

Version: 0 Date: 18 Aug 2019

Reviewer: Bil Kirmani

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This is the study protocol for a prospective non-randomised multi-centre registry looking at the effects of DuraGraft solution on the outcomes of saphenous vein graft and free arterial grafts for patients undergoing isolated or concomitant coronary artery bypass grafting. This registry is being undertaken in parallel with a randomised controlled trial of the solution that will be used to corroborate the findings of a previous observational study.

The protocol is well written with excellent English throughout. There are a few typographic errors such as "neurological deficient" rather than "neurological deficit" in Table 1 and the unclosed bracket on line 49, page 7 which would be attended to in proofreading. Having said this, I would favour a more judicious use of parentheses to describe examples and exceptions throughout the paper, although this is a stylistic opinion only.

I have several comments about the protocol as it is presented:

p7,L58 - The registry has already begun collecting data and, as such, it would seem to be redundant to publish the study protocol nearly 3 years after it had begun.

p8,L38 - Which version of EuroSCORE?

p9,L20 - presumably the outcomes are both composite outcomes only?

The overall premise of the registry itself - to establish practices in CABG and define current multinational outcomes and methodologies is laudable. How that information will be utilised is less clear: if the registry shows a narrow confidence interval for the composite outcomes, in the absence of patency information, this may lead to the question about the sensitivity of the surrogate outcome measures. If, as I would guess, the confidence intervals are wide and there is evidence of variation between centres, correlating this with the results of the randomised controlled trial will be difficult and the temptation to undertake underpowered subgroup analyses will be great.

Although I agree that best practice is to publish protocols for studies, I do not know that the present submission adds enough to the existing protocol description on the trials website to warrant separate publication. However, the content - and the results of the registry - would be of
interest to the readers of the journal who may not otherwise be aware of the study and this would be the main reason to consider publication if the editors saw fit.

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An article of limited interest

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