Author's response to reviews

Title: Endoscopic Saphenous harvesting with an Open CO2 System (ESOS) Trial. Study design and rationale of a prospective randomized trial for coronary artery bypass grafting surgery

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Version: 4 Date: 24 October 2011

Author's response to reviews: see over
Authors’ response

Title: Endoscopic Saphenous harvesting with an Open CO2 System (ESOS)
Trial. Study design and rationale of a prospective randomized trial for coronary artery bypass grafting surgery
Version: 2 Date: 1 April 2011
Reviewer: lawrence friedman
Reviewer’s report:
I have reviewed this manuscript and have a few comments/questions:

a) In this unblinded trial, are there any procedures for assuring that outcome assessment is unbiased?

Reply: All data relative to enrolled patients are to be entered in a database and examined by an independent clinical committee every scheduled follow-up time.

b) It is unclear how the projected sample size is adequate for the 2-year endpoint. What are the expected MACE event rates? Is this being planned as a superiority or a noninferiority trial? If the former, what difference in MACE will be likely to be detected with 80% power? If the latter, what is the delta of noninferiority and why?

Reply:

1. On the basis of previous comparative trials of EVH versus OVH, none of the clinically relevant cardiovascular outcomes differed significantly for EVH compared with OVH (Allen et al.\textsuperscript{11} reported survival free of MACE at up to 5 years as 75\% vs. 74\%, p=0.85).

2. ESOS trial is being planned as a non-inferiority trial, as it is being explained in the foot of our “summery article” previously submitted.

3. In order to demonstrate non-inferiority, a delta of 2-3\% is planned in our protocol study. After study completion, a two-sided 95\% confidence interval for the true difference between the two treatments will be constructed. This interval should lie entirely on the positive side of the non-inferiority margin.
c) A more minor issue: in several places the abbreviations are used before they are spelled out.

d) The language is at times awkward and has some grammatical errors. The manuscript should be carefully edited by a native English speaker.

Reply: We appreciate reviewer’s suggestions regarding our grammatical mistakes and abbreviations. We have reviewed this manuscript and we have highlighted those mistakes.

We hope that our response to our revised manuscript is sufficient to obtain reviewer appreciation and consequent publication in this respectable “Trials” journal.

Sincerely, the Authors