Author’s response to reviews

Title: A phase II, Randomized, Sham-Controlled, Double-Blinded Trial Testing the Safety and Efficacy of the Coronary Sinus Reducer in Patients with Refractory Angina: Rationale and Design.

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Author’s response to reviews:

Dr Lawrence Friedman,

Thank you very for taking the time to review our manuscript

Comment a) On page 4, at the end of the first paragraph, there is mention of the need for new options. The reference given is now 13 years old. A newer reference would be useful.

Our response:

This is a good point. We have removed this reference and changed it for the recently reported 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for chronic stable angina, which reads as follow:


Comment b) Although the Trial Status on page 16 indicates that the participant accrual is
ongoing (as does the last paragraph on page 6), the last paragraph on page 7 uses verbs in the past tense, suggesting that accrual is complete. This should be clarified.

Our response:

We have changed the last paragraph on page 7 which now reads as follow:

“The final protocol and amendments as well as the consent form are reviewed and approved by the institutional review board and independent ethics committee at each participating center. The study is being conducted in compliance with the provisions of the Declaration of Helsinki and relevant local country regulations. All patients must provide written informed consent”

Comment c) The Abstract indicates that the primary outcome of angina improvement is at 6 months, but the time for the primary outcome is not indicated in either the Outcomes section (page 9) or Table 2. It would be useful to include the time in those places as well as the Abstract.

Our response:

The outcome section (page 9) has been modified and now reads as follow:

“Primary and secondary endpoints of the COSIRA trial are listed in Table II. The primary end points will compare the number of participants experiencing angina improvement #2 CCS grades 6 months after the intervention.

The table II has been modified as well.

Comment d) A statement of possible conflicts of interest of the authors should be included.

Our response:

The following statement has been added on page 16
Dr Henry, Dr White, Dr Edelman, have served on the scientific advisory board of Neovasc for the COSIRA trial. Dr Banai and Mr Schwartz are respectively the Medical Director and the Director of Clinical and Regulatory Affairs at Neovasc. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Comment e) The three tables are in the Supplementary Files. Although readily retrievable, they are important enough to be included with the main manuscript.

Our response: Correction made.

Comment f) A trivial issue: references 6, 7, 9, and 10 have the author names all in upper case, which is different from the rest of the references.

Our response: Corrections made.