Author's response to reviews

Title: Mechanochemical endovenous Ablation versus RADIOfreQuency Ablation in the treatment of primary great saphenous vein incompetence: MARADONA: study protocol for a randomized controlled trial

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Author's response to reviews:

Cover letter - Response to Reviewers

Dear Editors,

On 27th February, I received an email regarding the submission of our study protocol 'Mechanochemical endovenous ablation versus radiofrequency ablation in the treatment of primary great saphenous vein incompetence'.

The suggestions of the reviewers have been incorporated in the revised manuscript. In addition, answers to the questions are included below.

1. Please include the names of all ethical bodies that approved your study in the various centers involved. If you do not wish to list them all in the methods section, please include the list as an additional file and refer to this in the methods section.

Answer: In The Netherlands, a multicenter randomized trial is assessed and approved by only one Medical Ethics Committee. The Medical Ethics Committee of Nijmegen approved the study protocol on 16th August 2011. After the ethical approval, the feasibility of the study is checked by all local institutional boards of the participating centers. Therefore, the only ethical body that approved our study protocol is the Medical Ethics Committee of Nijmegen.

In the manuscript (page 6, ethical considerations) was written: “The study is approved by the Medical Ethics committee of Nijmegen (CMO 2011/091) and the local institutional board of each participating center.”

2. Please modify your Authors’ Contributions section to demonstrate that each author meets all three of the following criteria to qualify for authorship: Substantial contributions to: the conception or design of the work; or the
acquisition, analysis, or interpretation of data for the work; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published.

Answer: The authors’ contributions are changed in the manuscript (page 14, Authors’ contribution)

“RVE drafted the manuscript, initiated and designed the study, performs data acquisition and revised the manuscript. DB co-authored the writing of the manuscript, initiated and designed the study, and revised the manuscript. SH coordinating trial investigator, participated in the trial design and sample size calculation, performs data management and coordination between study centers, and revised the manuscript. AV contributed to the scientific accuracy of the manuscript, performs data acquisition, and revised the manuscript. JPV initiated and designed the study, performs data acquisition, and revised the manuscript. CZ contributed to the scientific accuracy of the manuscript, performs data acquisition, and revised the manuscript. MR responsible trial coordinator, initiated and designed the study, performs data acquisition and coordination between study centers, and revised the manuscript. All authors read and approved the final manuscript.”

3. Please include an acknowledgement section at the end of the manuscript before the reference list. Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include the source(s) of funding for all authors. Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements.

Answer: An acknowledgement section is added to the manuscript (page 15, Acknowledgements)

“The MARADONA trial is an investigator-sponsored study supported by Vascular Insights Ltd. The authors declare they did not receive any personal payment related to any subject of the study.

We are grateful to the members of the Medical Ethics committee and Data Safety Monitoring Board for their input.”

We hope the answers to the questions are sufficient and the Trials Journal is still interested in publishing our study protocol.

With regards,
On behalf of our study group,
Ramon van Eekeren