Author’s response to reviews

Title: Covered Stents versus Bare-Metal Stents in Chronic Atherosclerotic Gastrointestinal Ischemia (CoBaGI): study protocol for a randomized controlled trial

Authors:
Louisa van Dijk (l.vandijk@erasusmc.nl)
Jihan Harki (j.harki@erasusmc.nl)
Desirée van Noord (D.Leemreis@franciscus.nl)
Hence Verhagen (h.verhagen@erasusmc.nl)
Jeroen Kolkman (J.Kolkman@mst.nl)
Robert Geelkerken (R.Geelkerken@mst.nl)
Marco Bruno (m.bruno@erasusmc.nl)
Adriaan Moelker (a.moelker@erasusmc.nl)

Version: 1 Date: 13 Jul 2019

Author’s response to reviews:

Response to Reviewers TRLS-D-18-00882

Reviewer 1
Answer: We thank Reviewer 1 for the careful review.

Reviewer 2
While I agree with the sample size estimation, assuming I have interpreted the description of sample size correctly, I think the text can be clarified - e.g. "Assuming that CS improves the patency rate of BMS after 24 months from 63% to 95%, and accounting for a 20% dropout rate, x participants are required per arm to achieve 80% power with a two-sided alpha of 0.05"
Answer: We thank Reviewer 2 for the careful review. Reviewer 2 has interpreted the description of the sample size correctly and we clarified the main text, please see the revised manuscript, page 15, lines 2-10:

The sample size calculation for this randomized controlled superiority trial is based on the retrospective data of Oderich et al[21]. Assuming that CS improves the patency rate of BMS after 24 months from 63% to 95%, and accounting for a 20% dropout rate, 42 participants are required per arm to achieve 80% power with a two-sided alpha of 0.05. The sample size calculation is performed using the Comparison of Independent proportions test (SAS Power and Sample size, SAS Institute Inc, Cary, NC, USA). “