Reviewer’s report

Title: Stereotactic Ablative Radiotherapy for the Comprehensive Treatment of 4-10 Oligometastatic Tumors (SABR-COMET-10): Study Protocol for a Randomized Phase III Trial

Version: 0 Date: 23 May 2019

Reviewer: Roy Decker

Reviewer’s report:

The authors present a planned/ongoing multi-institutional phase III trial of comprehensive SABR for patient with limited metastatic disease, here defined as 4-10 metastatic lesions. This is an exciting and novel study which is a natural extension of the authors' recently published phase II SABR-COMET study. The first SABR-COMET demonstrated improved OS (median 28 months versus 41 months for SABR), but did report 3 treatment-related deaths in the experimental arm. While the study included up to 5 metastatic sites, it was primarily populated with patients with 1 to 3 targets. The proposed 159 patient study includes a 2:1 randomization to SABR versus standard-of-care, and is appropriately powered for a primary endpoint of overall survival. The author have a companion SABR-COMET3 and plan to do secondary combined analyses, and there are included translational studies that are potential biomarkers.

This is an exciting study, though it may face some of the same challenges to accrual noted in previous randomized oligometastatic trials.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
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Yes

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