Reviewer’s report

Title: Transarterial RAdioembolization versus ChemoEmbolization for the treatment of hepatocellular carcinoma (TRACE): study protocol for a randomized controlled trial

Version: 1 Date: 4 March 2012

Reviewer: Rakesh Aggarwal

Reviewer’s report:

The protocol is generally well written. I have the following suggestions:

Major Compulsory Revisions

1. Sample size calculation: All assumptions made for such calculation and the details of the software etc used for this calculation should be provided. The drop-out rate of 2% assumed for each group appears to be quite small. The authors need to recheck this part of the manuscript.

Minor Essential Revisions

2. The background information on TACE refers to ‘post-embolization syndrome’. It may help to explain what this phrase means. This may be useful to some readers who are relatively unfamiliar with this treatment modality.

3. The minimization procedure will be done using a ‘validated software’. Is this software available commercially? If yes, the name and source may be added.

4. The methods for TACE state that ‘A target dose of 100-150 mg doxorubicin per patient is intended’. The factors determining the drug dose within this range (e.g. who will receive 100 mg and who will receive 150 mg) may be specified. For instance, will this be based on body weight or surface area.

5. The methods for 90Y-RE state that: ‘The required activity according to the package insert is calculated based on the target volume’. It would be useful to provide the details of this within the manuscript, so that a reader can understand this without reference to the package insert of the particular commercial product.

6. The methods state that: ‘Laboratory examination will be performed on a regular basis’. It may be useful to state what all examinations will be done.

7. Some parts of treatment for Y-RE are in present tense. These should preferably be in future tense.

8. Background, paragraph 1: ‘Curation is only achieved by …’ can be changed to ‘Cure is achieved only by …’.

9. Page 6, line 6: The text ‘…stated in a meta-analyse of RCTs …’ can be
changed to ‘…stated in a meta-analysis of RCTs …’.

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I have no competing interests in relation to this manuscript.