Reviewer’s report

Title: Transperineal prostate brachytherapy, using I-125 seed with or without adjuvant androgen deprivation, in patients with intermediate-risk prostate cancer: study protocol for a phase III, multicenter, randomized, controlled trial

Version: 2 Date: 23 June 2010

Reviewer: Charles Rosser

Reviewer's report:

Miki et al report the design of an ongoing phase III multicenter randomize trial of ADT + brachytherapy vs. brachytherapy alone in men with intermediate risk prostate. The authors clearly highlight how the use of ADT in patients with intermediate prostate cancer is controversial. Thus the authors have designed a study to finally and clearly answer the question, is ADT needed with brachytherapy in men undergoing brachytherapy. This is a well thought out, well written article from a strong group of investigators. Below is a point by point critique of the manuscript.

• Major Compulsory Revisions

NONE

• Minor Essential Revisions

It would help if the authors included a figure of the study schema. The current figure is of little use. I would delete it.

Reference (5) is near the beginning of a paragrapg however almost the entire paragraph is related to reference (5). I would move reference (5) to after sentence…Furthermore, symptoms persisted…

• Discretionary Revisions

Despite the authors’ rationalization why 3 months of ADT is given to all study participants I still do not understand nor do I agree with it. The use of ADT in this setting may skew results albeit for both group, but I still wonder do we even need the initial 3 months of ADT?

• I think the addition of prostate biopsies after therapy greatly strengthens the proposal. I am unsure why this part of the protocol has a different title. I would have thought the biopsies could have been a sub-aim in 804.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
'I declare that I have no competing interests'