Reviewer's report

Title: Role of cytarabine in paediatric acute promyelocytic leukemia treated with the combination of all-trans retinoic acid and arsenic trioxide: a randomized controlled trial

Version: 0 Date: 03 Nov 2017

Reviewer: Scott C Kogan

Reviewer's report:

The authors present the results of clinical trial of APL in children in which RA, arsenic and anthracycline therapy are compared to RA, arsenic, anthracycline and cytosine arabinoside. Both study groups showed excellent outcomes. Although there have been advances in treatment of APL since the initiation of this trial, the results are nevertheless important to be made available to the medical and research communities. The work adds to the published literature by assessing response to treatment and outcomes in a substantial group of children.

The authors retrospectively registered this study in August of 2010, just a few months after initiation of the trial in May of 2010. The authors have clearly and appropriately declared this information and it does not impact interpretation of the results.

Suggestions for revision.

1. Line 208. The authors intended "Induction therapy" here, not "Introduction therapy."

2. Line 255. Suggested revision "During consolidation, no blood product was required in the no-Ara-C group.

3. Lines 268-269. Suggested revision. After the third consolidation cycle (i.e. the first cycle of DNR/DA), a complete remission (molecular) was achieved in all patients (Fig. 1). Suggest to omit the last sentence of this paragraph beginning "All of the patients tested..." on line 271 as repetitive and not needed.

4. Lines 294-297. Not entirely clear whether the authors mean that the median levels are not significantly different or mean that the groups are not significantly different. Correct as written? If correct as written, authors should state that the groups are not significantly different (by either one-sided t-test or similar appropriate analysis).
5. Line 512. Spelling of "enrollment" should be corrected.

6. Figure 1: It could be of use to the reader to indicate the protocol planned days from first initiation of induction to the start of each of the 4 cycles of consolidation and to the beginning of maintenance.

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?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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