Reviewer’s report

Title: Low-dose decitabine priming with intermediate-dose cytarabine followed by umbilical cord blood infusion as consolidation therapy for elderly patients with acute myeloid leukemia: a phase II single-arm study.

Version: 0 Date: 04 Mar 2019

Reviewer: Houda Alachkar

Reviewer's report:

This is a well written manuscript reporting on the outcome of a phase II clinical trial that combined Low-dose decitabine priming with intermediate-dose cytarabine followed by umbilical cord blood infusion as consolidation therapy for elderly patients with acute myeloid leukemia. Testing of this combination is important to the field, however the follow-up time is only one year. This is considered short in AML clinical trials and should be expanded to at least 2 years.

Additional comments that could improve the manuscripts are:

Introduction

It would be helpful to add details related to the rationale for the particular design of the clinical trial, why they selected low-dose decitabine versus regular dose, and why the intermediate-dose cytarabine, what are the previous trials that showed any potential clinical benefit that suggested this combination would be beneficial? Are there any ongoing/previous clinical trials with similar combination, how this differ?

Methods;

Please provide more details related to the monitoring of the minimum residual disease, what surface antigens they looked at.

Results:

- Treatment outcome by MRD level: this result section could be expanded to explain what is included in the MRD values, what markers were used.
- Table 1 should be expanded to include % blasts in blood, Bone marrow at diagnosis and at remission. Also FLT3-ITD status, NPM1, other mutations as well, cytogenetic status.

- Expand on the results related to table 2 (toxicities) and how it compares with control group both in the results section and the discussion.

- Also, I recommend moving the supplementary figure to regular figures.

- One year overall survival is very low, there is no clear significant evidence that this has greatly improved outcome in such that it should move to phase III at this point and before a longer study is done. Further analysis at the 2 years cut-off should be established (June 2019) before this data is published.

- A table of patients receiving different treatments, not the trial protocol, also for patients in the control group.

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 recommend additional statistical review

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Please indicate the quality of language in the manuscript:

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