Reviewer's report

Title: Gemcitabine and docetaxel combination chemotherapy for advanced bone and soft tissue sarcomas: protocol for an open-label, non-randomised, Phase 2 study

Version: 0 Date: 24 Mar 2019

Reviewer: Sandro Pasquali

Reviewer's report:

This is the presentation of a protocol. There are some methodological issues that authors should clarify and improve.

Major comments:

The most controversial issue with this study is the main endpoint. The authors stated that their primary endpoint is PFS but then the sample size calculation is based on response rate. This is confusing. Also, this is a phase II study which electively looks at response rather than survival. The authors should clarify their study design and select their main endpoint to perform sample size calculation consistently.

It would be appropriate to have histological confirmation of metastasis with a biopsy.

The study should be registered in clinicaltrial.gov

The title should mention that patients were pretreated.

The Background section results quite awkward as it started with two type of sarcoma rather than giving the reader a general idea of treatment of metastatic sarcoma. Authors should report median survival of metastatic STS and offered also example of survival variations according to hystoyypes. Then they should reported common chemotherapy regimens which are usually based on anthracycline. Then, they should mention that the different spectrum of sarcomas are sensitive to different chemotherapy regimens. At this point it is worth reporting on osteo and Ewing as well as some soft tissue sarcomas such as leiomyosarcoma. Their study is about both bone and soft tissue sarcoma rather than single histologies.

Line 52 to 69 have no references which need to be added.
Minor comments


References for RECIST and CTCAE should be added.

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.

No

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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Please indicate the quality of language in the manuscript:

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