Reviewer’s report

Title: A double-blind randomized comparative clinical trial to evaluate the safety and efficacy of dendritic cell vaccine loaded with WT1 peptides (TLP0-001) in combination with S-1 in patients with advanced pancreatic cancer refractory to standard chemotherapy

Version: 0 Date: 23 Jan 2019

Reviewer: Kazuo Koyanagi

Reviewer's report:

This was a protocol manuscript of multicenter, randomized, and double-blind, controlled trial of a dendritic cell vaccine loaded with Wilms' tumor gene 1 (WT1) peptides (TLP0-001) as a potential vaccine therapy for patients with advanced pancreatic cancer refractory. This trial is attractive, because promising chemotherapy regimens are few for the pancreatic cancer. However, there were several issues that we could not understand from this manuscript, such as safety of TLP0-001, DLT of combination with S-1. Basically, randomized controlled trial should be conducted based on the results of phase I/II studies. The authors should clarify in the manuscript. Followings are my comments and questions.

Comments;

1. As the authors described, this is the first-in human clinical trial of TLP0-001. I think the authors have investigated the safety of the vaccine before this trial. So, they should describe it in the Background or Discussion section.

2. Also, this is the first trial of TLP0-001 combined with S-1. The authors should describe how they decided the administration dose of S-1. Did the authors have the results of dose escalation study?

3. How did the authors randomize the patients? Please describe the factors that were used for the adjustment of the patients.

4. Are there any provision of surgical options in the protocol, if the tumor decreases and can be resected.

Level of interest

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