Vojnosanitetski pregled
Editorial Office/ Editorial Staff
Military Medical Academy, INI
Crnotravska 17, PO Box 33-55 11040 Belgrade Serbia
Ph: +381 11 3609 311, 3608 943 Fax: +381 11 2669 689

CC: Prof Dr Silva Dobric, Editor-in-chief

10/04/2013

Dear Sir/Madam,

Re: Submission of a new manuscript – Original Research
VSP 3730/2013

Following the *Decision Letter for manuscript VSP 3332/2012,* received by e-mail on 12th March 2013, this is to address the Reviewers' comments and outline the improvements reflected in the new manuscript *VSP 3730/2013*.

The title of the manuscript is:

Manufacturing and use of human placenta-derived mesenchymal stromal cells for phase I clinical trials: establishment and evaluation of a protocol.

Reviewers' Suggestions to Author related to *VSP 3332/2012*, were stringently analysed and followed.

Specific comments below were addressed in the new manuscript, as follows:

Reviewer's Comment (1): " ... According to manuscript structure - this is not general review, nor original paper. … Uvod / Introduction: Too large, 4 ps. mor than 1100 words. … Bibliografija / Reference: Except 7 data from 2012 (one from 2013), generally old references. …"

Reviewer's Comment (2): " … This is an article with mixed features of a review article, description of a manufacturing process and of a clinical trial phase I report. Although it is written in good English language and with good style, it is unsuitable

for publication in VSP in the present shape, for the following reasons: it is too long and elaborate for a medical journal article; there are many details on manufacturing process with photographs which are suitable for documentation of a laboratory procedure or guideline, but not for a journal article; the phase I trials on just a few patients are described without necessary details, e.g. the outcomes of the patients are missing, the controls are missing, etc.; it was not clearly stated how long were the patients followed after infusion of MSC, and what check-ups were performed to exclude late adverse effects of the MSCs; Introduction and Discussion are not focused, as well as the title and the article itself: was it manufacturing process, or results of early clinical trials? … ".

Correction of the manuscript

The manuscript has been rewritten in order to address all of the reviewers' comments and establish the format and content more appropriate to the VSP journal original research articles.

The text of the manuscript is 10 pages long (3,700 words in total), images have been limited to scientific data or presentation of the results, and references have been updated.

The entire manuscript is written around the manufacturing protocol establishment and its clinical evaluation. This is reflected in the manuscript new title '*Manufacturing and use of human placenta-derived mesenchymal stromal cells for phase I clinical trials: establishment and evaluation of a protocol'*.

Although some of the clinical trials have been presented briefly as part of protocol evaluation, it is important to note that clinical trial design and clinical outcomes (other than safety), patient inclusion and exclusion criteria, patient follow-up, relevant controls and clinical parameters were beyond the scope of this paper.

Thank you for the opportunity to submit the revised version as a new manuscript VSP 3730/2013.

Sincerely,

Nina Ilic
Mater Health Services
South Brisbane QLD 4101 Australia
Email: Nina.Ilic@mater.org.au
Mob: +61 417209563