Reviewer’s report

Title: Treatment with Pirfenidone for two years decreases fibrosis, cytokine levels and enhances CB2 expression in patients with chronic hepatitis C: open-label clinical trial

Version: 2
Date: 23 December 2013
Reviewer: Chao-Hung Hung

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Major Compulsory Revisions

In this manuscript, the authors aimed to assess whether two-year treatment with pirfenidone influence necro-inflammation, fibrosis and steatosis, as well as serum markers in patients with chronic hepatitis C (CHC). They found that pirfenidone for two years benefits CHC patients and improves inflammation, fibrosis and steatosis. Although their data seem logical, there are several issues that should be further reconsidered or corrected.

1. The major criticism raised is the high rate (18%) of early termination from this study. What happened in these subjects with early discontinuation? Was there any severe adverse effect associated with study medication? What were the causes for the mortality?

2. Intention-to-treat analyses should be performed, including liver biochemistry, clinical status, and serum biomarkers.

3. The authors should provide the statistical analyses on the Child-pugh status and quality of life between before and after treatment (table 2).

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests