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315-321 Lockhart Road, Wan Chai, Hong Kong, China

ESPS Peer-review Report

Name of Journal: World Journal of Hepatology

ESPS Manuscript NO: 8207

Title: Pegylated interferon alpha-2b plus ribavirin therapy in treatment of chronic hepatitis C

Reviewer code: 02453015

Science editor: Zhai, Huan-Huan

Date sent for review: 2013-12-22 19:47

Date reviewed: 2014-02-16 21:00

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
<input type="checkbox"/> Grade A (Excellent)	<input type="checkbox"/> Grade A: Priority Publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B (Very good)	<input type="checkbox"/> Grade B: minor language polishing	<input type="checkbox"/> Existed	<input type="checkbox"/> High priority for publication
<input type="checkbox"/> Grade C (Good)	<input checked="" type="checkbox"/> Grade C: a great deal of language polishing	<input type="checkbox"/> No records	<input checked="" type="checkbox"/> Rejection
<input type="checkbox"/> Grade D (Fair)		BPG Search:	<input type="checkbox"/> Minor revision
<input checked="" type="checkbox"/> Grade E (Poor)	<input type="checkbox"/> Grade D: rejected	<input type="checkbox"/> Existed	<input type="checkbox"/> Major revision
		<input type="checkbox"/> No records	

COMMENTS TO AUTHORS

This is a straightforward clinical control study. Major concerns: 1. Sample size. According to pre-study calculation, 100 participants are needed. However, only 82 completed the study. Is this number enough to show significant difference with the pre-designed power? 2. A stratified statistical analysis is recommended according to the level of HCV copy. 3. No statistical conclusion is made. No p value is shown. Therefore, audience are not sure about the efficacy of the treatment. 4. English needs to be improved.



ESPS Peer-review Report

Name of Journal: World Journal of Hepatology

ESPS Manuscript NO: 8207

Title: Pegylated interferon alpha-2b plus ribavirin therapy in treatment of chronic hepatitis C

Reviewer code: 00012386

Science editor: Zhai, Huan-Huan

Date sent for review: 2013-12-22 19:47

Date reviewed: 2014-02-16 22:00

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
<input type="checkbox"/> Grade A (Excellent)	<input type="checkbox"/> Grade A: Priority Publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B (Very good)	<input checked="" type="checkbox"/> Grade B: minor language polishing	<input type="checkbox"/> Existed	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C (Good)	<input type="checkbox"/> Grade C: a great deal of language polishing	<input type="checkbox"/> No records	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D (Fair)		BPG Search:	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade E (Poor)	<input type="checkbox"/> Grade D: rejected	<input type="checkbox"/> Existed	<input checked="" type="checkbox"/> Minor revision
		<input type="checkbox"/> No records	<input type="checkbox"/> Major revision

COMMENTS TO AUTHORS

This manuscript includes the important data of SOC treatment for HCV genotype 3 from India. 1. Authors should analyze the data of HCV genotypes 1, 3, and 4 separately 2. In Introduction, Authors should delete the following sentence: In view of this, to provide quality healthcare at an affordable cost, Virchow Biotech, an ANVISA Good Manufacturing Practices certified company, developed pegylated interferon alfa-2b from E. coli by using recombinant DNA technology. 2. Authors should update the references because the references look relatively old. The following references should be added. 1) Kanda T, Nakamoto S, Nishino T, Takada N, Tsubota A, Kato K, Miyamura T, Maruoka D, Wu S, Tanaka T, Arai M, Mikami S, Fujiwara K, Imazeki F, Yokosuka O. Peginterferon Alfa-2a plus ribavirin in Japanese patients infected with hepatitis C virus genotype 2 who failed previous interferon therapy. *Int J Med Sci.* 2013;10(1):43-9. doi: 10.7150/ijms.5358. 2) Kanda T, Imazeki F, Azemoto R, Yonemitsu Y, Mikami S, Kita K, Takashi M, Sunaga M, Wu S, Nakamoto S, Tawada A, Arai M, Kato K, Yoshida Y, Koma Y, Fujiwara K, Fukai K, Suzuki N, Yokosuka O. Response to peginterferon-alfa 2b and ribavirin in Japanese patients with chronic hepatitis C genotype 2. *Dig Dis Sci.* 2011 Nov;56(11):3335-42. doi: 10.1007/s10620-011-1750-7. 3) Kanda T, Imazeki F, Yokosuka O. New antiviral therapies for chronic hepatitis C. *Hepatol Int.* 2010 Aug 19;4(3):548-61. doi: 10.1007/s12072-010-9193-3. The APASL guideline and AASLD updated guideline for HCV treatment should also be included. 1) APASL Guidelines for HCV (*Hepatol Int* 2012; 6: 409-435) <http://apasl.info/guidelines> 2) Ghany, M. G., Nelson, D. R., Strader, D. B., Thomas, D. L. and Seeff, L. B. (2011), An update on treatment of genotype 1 chronic hepatitis C virus infection: 2011 practice guideline by the American Association for the Study of Liver Diseases. *Hepatology*, 54: 1433-1444.



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ESPS Peer-review Report

Name of Journal: World Journal of Hepatology

ESPS Manuscript NO: 8207

Title: Pegylated interferon alpha-2b plus ribavirin therapy in treatment of chronic hepatitis C

Reviewer code: 00094071

Science editor: Zhai, Huan-Huan

Date sent for review: 2013-12-22 19:47

Date reviewed: 2014-02-24 23:10

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
<input type="checkbox"/> Grade A (Excellent)	<input type="checkbox"/> Grade A: Priority Publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B (Very good)	<input checked="" type="checkbox"/> Grade B: minor language polishing	<input type="checkbox"/> Existed	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C (Good)	<input type="checkbox"/> Grade C: a great deal of language polishing	<input type="checkbox"/> No records	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D (Fair)		BPG Search:	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade E (Poor)	<input type="checkbox"/> Grade D: rejected	<input type="checkbox"/> Existed	<input checked="" type="checkbox"/> Minor revision
		<input type="checkbox"/> No records	<input type="checkbox"/> Major revision

COMMENTS TO AUTHORS

The methods section describes inclusion and exclusion criteria, but does not explain the selection process (consecutive, random...?). Please add. Other limitations include: non-randomised, non-blinded, non-controlled, small sample size, and exclusion of important patient groups (e.g. HIV co-infection). Considering that the main rationale for this study is to identify a more cost effective alternative source of peg-IFN, the cost of this generic version should be stated and compared against the cost charged by the original company. It is also unclear if the Virchow product is already registered and in use in India, or in other countries



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ESPS Peer-review Report

Name of Journal: World Journal of Hepatology

ESPS Manuscript NO: 8207

Title: Pegylated interferon alpha-2b plus ribavirin therapy in treatment of chronic hepatitis C

Reviewer code: 01560565

Science editor: Zhai, Huan-Huan

Date sent for review: 2013-12-22 19:47

Date reviewed: 2014-02-26 17:06

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
<input type="checkbox"/> Grade A (Excellent)	<input type="checkbox"/> Grade A: Priority Publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B (Very good)	<input type="checkbox"/> Grade B: minor language polishing	<input type="checkbox"/> Existed	<input type="checkbox"/> High priority for publication
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<input type="checkbox"/> Grade E (Poor)	<input type="checkbox"/> Grade D: rejected	<input type="checkbox"/> Existed	<input type="checkbox"/> Major revision
		<input type="checkbox"/> No records	

COMMENTS TO AUTHORS

General comments: Hepatitis C virus infection is a globally health problem, and peg-interferon alfa plus ribavirin combination therapy remains the standard of care in many Asian countries. Currently, the treatment outcomes using this combination therapy and the related side effects are well known. This study just tried to report the treatment results and safety profiles using a locally produced peg-interferon in the treatment regimen. Overall, the study concept was not novel. Besides, the study design was not sound. It was not a randomized study and the case number was small. Suggestions: 1. In addition to ITT analysis, per protocol analysis should also be done and reported. 2. The discussion part can be shortened.