



ESPS PEER REVIEW REPORT

Name of journal: World Journal of Gastroenterology

ESPS manuscript NO: 13027

Title: ORAL ADMINISTRATION OF ALEQUEL?, A MIXTURE OF AUTOLOGOUS COLON-EXTRACTED PROTEINS, FOR THE TREATMENT OF CROHN’S DISEASE: RESULTS OF A DOUBLE-BLIND CLINICAL TRIAL

Reviewer code: 02445675

Science editor: Su-Xin Gou

Date sent for review: 2014-08-02 20:18

Date reviewed: 2014-08-04 02:10

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input checked="" 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"/> Existing	<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	<input type="checkbox"/> Grade D: Rejected	BPG Search:	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> Existing	<input type="checkbox"/> Major revision
		<input type="checkbox"/> No records	

COMMENTS TO AUTHORS

ESPS Manuscript NO: 13027 Title: ORAL ADMINISTRATION OF ALEQUEL, A MIXTURE OF AUTOLOGOUS COLON-EXTRACTED PROTEINS, FOR THE TREATMENT OF CROHN’S DISEASE: RESULTS OF A DOUBLE-BLIND CLINICAL TRIAL This paper addresses an important and widely-investigated area dealing with the pharmacological treatment of Crohn’s disease. In their article, the Authors describe the results of a controlled double-blind trial of oral administration of the autologous colonic extract that was shown to be effective for the treatment of patients with moderate to severe CD. The Authors well describe all the diagnostic procedures they adopted and the methods for the Study Drug Preparation and Administration However, there are some issues that need to be reviewed to make the paper suitable for publication on WJG

- 1) The authors should include some inflammatory parameters (i.e., mean CRP and ESR levels) at enrollment and during follow up (6-9-12 weeks) in the drug and placebo group in order to help evaluating clinical response or remission.
- 2) Provide an endoscopic assessment at enrollment and during follow up, at least for patients with a colonic localization of the disease, in order to evaluate mucosal healing that is today considered the main goal of any IBD-treatment
- 3) Provide data regarding the steroid sparing-effect of the drug respect to placebo
- 4) Improve the statistical analysis using p evaluation (put the numbers)
- 5) Modify reference paragraph (it’s written according Hebrew order from right to



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left) 6) Improve the figures and figures legend including p values (even if there is not statistically difference among groups) In my opinion, in order to reach the standard of papers usually accepted for publication in WJG, the Authors should provide responses to these many comments. I thank you for considering me as reviewer for this manuscript. Best regards.



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Reviewer code: 02508740

Science editor: Su-Xin Gou

Date sent for review: 2014-08-02 20:18

Date reviewed: 2014-08-15 20:19

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input checked="" 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"/> Existing	<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	<input type="checkbox"/> Grade D: Rejected	BPG Search:	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> Existing	<input type="checkbox"/> Major revision
		<input type="checkbox"/> No records	

COMMENTS TO AUTHORS

Manuscript “ ORAL ADMINISTRATION OF ALEQUEL, A MIXTURE OF AUTOLOGOUS COLON-EXTRACTED PROTEINS, FOR THE TREATMENT OF CROHN’S DISEASE: RESULTS OF A DOUBLE-BLIND CLINICAL TRIAL” take an important role of biological treatment in Crohn’s disease, but I pay attention on that there is no CRP protein value, which is very simple and sensitive parameter. The Authors should estimate endoscopic evaluation of mucosal healing, because at the moment it is the most important goal with IBD treatment. I think that p value should be also used in statistical analysis and change reference - numbers should be on the opposite site.



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Reviewer code: 00069618

Science editor: Su-Xin Gou

Date sent for review: 2014-08-02 20:18

Date reviewed: 2014-08-17 01:35

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input checked="" type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input checked="" type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> Existing	<input type="checkbox"/> High priority for publication
<input 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	<input type="checkbox"/> Grade D: Rejected	BPG Search:	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> Existing	<input type="checkbox"/> Major revision
		<input type="checkbox"/> No records	

COMMENTS TO AUTHORS

The paper is quite of interest and also original in design, even if the sample size is small. The Author should better describe how they prepared the colon-specific antigen-containing extract. Furthermore if the extract can be administered at meal or fasting.



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Reviewer code: 00036648

Science editor: Su-Xin Gou

Date sent for review: 2014-08-02 20:18

Date reviewed: 2014-08-12 09:05

CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input checked="" 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"/> Existing	<input type="checkbox"/> High priority for publication
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<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> Existing	<input type="checkbox"/> Major revision
		<input type="checkbox"/> No records	

COMMENTS TO AUTHORS

This manuscript bears very similar resemblance to a phase 2 study evaluating Alequel which was published in American Journal Gastroenterology 2006 by the same group (Margalit et al, Am J Gastroenterol 2006;101:561-568). Thus I am confused why the authors would re-do(?) this study in a rather inferior way to the study above, and clearly with insufficient power to detect what should have been anticipated to be a fairly mild benefit (if any) with Alequel over placebo, given the previous study's results. This has culminated in a negative study which does not add to the current literature, given the almost identical study was already done in 2006.