OPEN PEER REVIEW

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Archives of Clinical Infectious Diseases
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Peer Review Report for "Accelerating Effects of Vitamin E Supplementation on Liver Enzyme Normalization in Children with Acute Hepatitis A Infection; a Single-Blinded Clinical Trial"

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Review Timeline:

- Submit Date: 4 Feb 2020
- Revised Date: 5 Oct 2020
- Accepted Date: 8 Nov 2020

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | Revision (0) 15 Jun 2020

Dear AE,
Totally it is an important article but What is the aim of the author to postulate?. ALT is the important indicator of hepatic function. Is its decrease important in the healing process of patients.? Please follow the format of the article based on the order of titles. A major revision is needed to show what is the importance of change in ALT in the clinical course of HAV patients with encephalopathy or coagulopathy?
- ABSTRACT: please write keywords based on mesh
- Background: please describe researches on the effect of vit e on hepatitis and / or other viral diseases.
Method:
- Inclusion criteria say that the author selected the patients with complicated hepatitis (coagulopathy and/or encephalopathy) did you have this large number of patients with encephalopathy or coagulopathy? What are your criteria for encephalopathy and

coagulopathy
- Exclusion criteria: How did you find patients with more than 6 months of Hep A since you cannot predict the previous situation of patients that were tested for the first time? why did you exclude change of urine and feces color and abdominal pain? What is the reason? Why don't you exclude people with primary liver damage or other hepatitis cases?
- What were the clinical symptoms that were monitored?
- Please don't write the ethical approval at the beginning of the method part, ethical code was repeated twice, omit one of them plz.
- What did you do for blinding? Did you use the placebo?
- What about PT and PTT changes?
- Is this effect important on the clinical improvement of patient condition or other factors for example control of encephalopathy?
Discussion:
- Please explain more about decrease of ALT in two groups, this is confusing
- What is NASH and NAFLD?
- References: Add more uptodate references.
Best regards

REFEREE: Reviewer | **Revision** (0) 13 Jul 2020

Dear AE,
We would like to thank the authors for presenting a comprehensive paper.
- Structure of the article needs to be revised under the supervision of a professional person again.
Regards

REFEREE: Associate Editor | **Revision** (0) 27 Sep 2020

Dear EIC,
The manuscript is studied, and there are some comments which should be addressed by the author. According to the comments, the document needs major revision.
Kind regards,

REFEREE: EIC | **Revision** (0) 27 Sep 2020

Dear Author,
The reviewers' comments are mentioned. Please correct the details as mentioned above carefully according to reviewers' request.
Thanks.

OPEN PEER REVIEW

Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear Editor in chief; Archives of Clinical Infectious Diseases

I'm pleased to inform you that we have now prepared our revised manuscript according to the dear reviewer's comments, and here present our responses. Within the text of the revised manuscript, the comments of reviewer 1 has been addressed and highlighted in **yellow** and those of reviewers 2 in **green**.

Thank you for handling our manuscript.

Reviewer 1:
Dear author
Q1: Thank you for submission of "Accelerating Effects of Vitamin E Supplementation on Liver Enzymes Normalization in Children with Acute hepatitis A infection" article Totally it is an important article but What is the aim of the author to postulate?. ALT is the important indicator of hepatic function. Is its decrease important in the healing process of patients.? Please follow the format of the article based on the order of titles. A major revision is needed to show what is the importance of change in ALT in the clinical course of HAV patients with encephalopathy or coagulopathy?

Reply: Thank you for valuable comments. We addressed yours with yellow-highlighted. In general, ALT and AST are indicators of hepatic damage in the course of hepatitis infection. In the revised manuscript, we tried to address the mentioned issue by bringing up the results of some clinical trials and arguing their findings and comparing them with ours, and also managed to the format according to the titles. Both ALT and AST are important in monitoring liver damage in symptomatic or asymptomatic HAV patients. In this study, and because of the self-limiting nature of the disease, we included only those who were hospitalized because of symptoms (coagulopathy and encephalopathy) which were diagnosed based on findings of laboratory tests (PT and PTT, and EEG) and clinical examination by a hepatologist and neurologist (but data were not recorded at the time so we could not provide them). In fact, our only outcome was liver functional (AST and ALT).

Q2: ABSTRACT: please write keywords based on mesh

Reply: MeSH terms were replaced.

Q3: Background: please describe researches on the effect of vit e on hepatitis and / or other viral diseases.

Reply: Four clinical trials on the effects of Vit E in patients with viral hepatitis mentioned just before the objectives.

Q4: Method: inclusion criteria says that the author selected the patients with complicated hepatitis (coagulopathy and/or encephalopathy) did you have this large number of patients with encephalopathy or coagulopathy? What are your criteria for encephalopathy and coagulopathy.

Reply: These were patients who referred to our hospital ward to office during about two years, but they were under surveillance and follow up of the researcher (an experienced pediatric gastroenterologist and hepatologist who had been working on this for more than 10 years). Getting started with analysis of the data took us about two years (2016-2017). The criteria for coagulopathy and/or encephalopathy were based on coagulation tests and EEG. Highlighted in the text.

Q5: Exclusion criteria: How did you find patients with more than 6 months of Hep A since you cannot predict the previous situation of patients that were tested for the first time? why did you exclude change of urine and feces color and abdominal pain? What is the reason? Why don't you exclude people with primary liver damage or other hepatitis cases?

Reply: As mentioned we had under follow up many of these patients for long enough to be aware of their situation, and this is because in our region there are limited access to health facilities and doctors. Default, as we only assessed those with HAV infection, we therefore did not enter patients with any other causes of hepatitis. As celiac is a common disease here and its definite diagnosis need intestinal biopsy and this is not applicable in many of them, in this way we excluded those with probable celiac. Changes in color of urine and feces could have indicated other serious systemic diseases including CD (mentioned and highlighted).

Q6: What were the clinical symptoms that were monitored?

Reply: Clinical symptoms were monitored only during hospitalization. The main outcomes which were monitored were AST and ALT.

Q7: plz don't write the ethical approval at the beginning of the method part, ethical code was repeated twice, omit one of them plz.

Reply: Ethical statement at 3.7 section was omitted.

Q8: what did you do for blinding? Did you use the placebo?

Reply: Only the researcher who measured liver enzymes was unaware of patients' grouping. So, it is a single-blinded trial. Added in 3.4 section and also in the title.

Q9: What about PT and PTT changes?

Reply: Please check the reply to **Q1**.

Q10: Is this effect important on the clinical improvement of patient condition or other factors for example control of encephalopathy?

Reply: Please check the reply to **Q1**.

Discussion:
Q11: plz explain more about decrease of ALT in two groups, this is confusing

Reply: In the revised version, we tried to avoid any confusing statement. In particular, in the first paragraph, we clearly write the message and finding of this study. (highlighted in green) and what was the pattern of AST and ALT changes. Following that, studies supporting the positive effects of vitamin E in various hepatic disorders, then probable mechanisms, and studies opposing these findings were mentioned.

Q12: What is NASH and NAFLD?

Reply: Abbreviations were provided. In the last paragraph of the background.

Q13: References: Add more uptodate references.

Reply: New and more recent references were provided (highlighted in the bibliography)

Reviewer 2:

Dear Associated editor
We would like to thank Authors for presenting a comprehensive paper.
Q1: Structure of the article needs to be revised under supervision of a professional person again.

Reply: Thank you for your comment, the structure was reviewed to address this issue. In the revised version, we tried to avoid any confusing statement. In particular, in the first paragraph, we clearly write the message and finding of this study. (highlighted in green) and what was the pattern of AST and ALT changes. Following that, studies supporting the positive effects of vitamin E in various hepatic disorders, then probable mechanisms, and studies opposing these findings were mentioned.

Associate Editor's Comments:

Associate Editor 1: Major revision

Reply: Revision was uploaded.

EIC Decision:

major revision

Reply: Revision was uploaded.

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Revision (1)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

Masoud Mardani: EIC | **Revision (1)** 8 Nov 2020

Dear Author,
The document is reviewed carefully by the reviewers. According to their comments and your revisions as requested, this manuscript is accepted.
Thanks.