Author’s response to reviews

Title: Effectiveness and Safety of Ferric Carboxymaltose Compared to Iron Sucrose in Women with Iron Deficiency Anemia: Phase IV Clinical Trials

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Author’s response to reviews:

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Dear Editor,

The manuscript "Effectiveness and Safety of Ferric Carboxymaltose Compared to Iron Sucrose in Women with Iron Deficiency Anemia: Phase IV Clinical Trials" (BMWH-D-17-00245R1) has been revised on the basis of referees comments and is submitted for your perusal.

1. Comment: Good to include worldwide prevalence of IDA both in general and special population (including pregnancy)

Reply: Worldwide prevalence of IDA both in general and special population has been added to the main manuscript file on page 3, paragraph 1.

2. Comment: How do you measure all of this? there is a slight confusion and mix up between aims and objectives. Aim is your overall goal and Objectives is how you reach your aim, and need to be measurable.
Reply: The aim and objectives have been revised as stated and mentioned accordingly.

3. Comment: Is the tool validated, etc. piloting the tool with experts which will help you to tailor to your setting.

Reply: The validation of the tool has been done from literature, with the experts at the institution and also discussed with the institutional ethical committee. The reference has been provided.

4. Comment: Require complete description of methodology: setting, sampling frame work, recruitment, procedure/protocol to standardize the practice and how and who will be involved in choosing and administering the drug.

Reply: Everything has been provided and necessary details have been updated in a manuscript. The text has been high lightened. Also, the figure 1 has been added, which outlines the entire procedure.

5. Comment: This should go up and continue with " where"

Reply: has been corrected.

6. Comment: Is test dose required for FCM????

Reply: Yes, test dose is required and reason for same has been provided and supported with reference.

7. Comment: Need to specify both independent and dependent variables and describe the analytic test accordingly.

Reply: Statistical Analysis has been revised, parameters individually written and all the statistical tests applied have been mentioned in detail.

8. Comment: Any data on this ???? (quality of life)

Reply: Data available have been updated, the scale used for its validation and procedure for evaluation of quality of life: all have been provided.
Comment: what was the measure ???

Reply: Measures required to evaluate the markers have been updated and given in detail in manuscript.

9. Comment: These reported events are for which preparation ???

Reply: They were for iron sucrose preparation and same has been updated and corrected.

10. Comment: Conclusion was not clear

Reply: Conclusion has been rewritten precisely and in clear language.

11. Comment: Also role of diet.

Reply: Patients were counselled for adequate iron rich diet has been updated and provided in the manuscript.

12. Comment: It is essential to have long term data as most of iron deficiency is long term.

Reply: The work was to compare the safety and effectiveness of the drugs in the attainment of normal levels of laboratory markers with respect to time and that has been adequately reported. Long term therapy was not taken into consideration as most of the patients who got their laboratory biomarkers corrected avoided further hospital visits.

13. Comment: Specific menstrual history

Reply: Specific menstrual history has been added in Table 1

14. Comment 1: “I would have preferred measurement of ferritin as baseline and change in it over time

Reply: Ferritin measurements have already been reported in the manuscript and that too with respect to the time only. Figure 5 in the manuscript gives the ferritin levels in the serum, also known as serum ferritin levels other than “Ferritin levels”.
Ferritin: is an intracellular iron storage protein and a marker of iron stores. Ferritin is found in most tissues as a cytosolic protein, but small amounts are secreted into the serum where it functions as an iron carrier. Plasma ferritin is also an indirect marker of the total amount of iron stored in the body, hence serum ferritin is used as a diagnostic test for iron-deficiency anemia.(1) Normal serum ferritin levels vary between laboratories but generally concentrations >300μg/L in men and postmenopausal women and >200 μg/L in premenopausal women are regarded as elevated. Low ferritin values provide absolute evidence of iron deficiency.(2,3)

References:

I look forward to publish my manuscript with BMC women’s health and please contact if you have any further query.

Best wishes

Ghulam N Bader
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