

Response to Letter to the Editor on: “The Effect of Ceratonia Siliqua L. on Semen Parameters in Idiopathic Male Infertility: A Systematic Review”

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ARTICLE INFO

Article type:

Letter to the editor

Article History:

Received: 30-June-2024

Accepted: 30-Jul-2024

► Please cite this paper as:

Asghari S, Taghipour A, Mahmoudinia M, Farshbaf-Khalili A, Latifnejad Roudsari R. Correction to: The Effect of Ceratonia Siliqua L. on Semen Parameters in Idiopathic Male Infertility: A Systematic Review. Journal of Midwifery and Reproductive Health. 2024; 12(3): 4276-4277. DOI: 10.22038/JMRH.2024.80864.2417

To the editor

We greatly appreciate the Journal of Midwifery and Reproductive Health policy of having an open forum where scientific disagreements can be discussed. Dr. Aghajani and his team raised two points concerning the risk of bias assessment of their published study (Aghajani et al. 2021) in our systematic review entitled: "The Effect of Ceratonia siliqua L. on Semen Parameters in Infertile Men: A Systematic Review" published in the Journal of Midwifery and Reproductive Health 2024; 12(1): 4006-4018 (1). Primarily, we really appreciate the consideration of this article and are grateful to the comments which have been very useful. Here, we discuss the issues raised by the authors of this letter to the editor.

Regarding assignment of "unclear" or "high" risk of bias for two items of random sequence generation and allocation concealment in the original article by Aghajani et al. 2021 entitled: "Comparison of the effect of Ceratonia siliqua L.(carob) syrup and vitamin E on sperm

parameters, oxidative stress index, and sex hormones in infertile men: A randomized controlled trial. Reproductive Sciences. 2021; 28(3): 766-774" (2), it should be noted that complete explanations regarding these two important items have not been provided in the original article and it has just been referred to the published study protocol of this clinical trial (Aghajani et al, 2019) (3), which was not implemented yet and we assumed that there is probably no guarantee to cover all randomization issues in the subsequent clinical trial.

Considering that we included the original study in our review, we assessed the risk of bias based on this article, which included insufficient information for the aforementioned items. Whereas, it was expected that more clarifications were provided for randomization to get a good quality score, as it is seen in most of the clinical trials published in quality international journals. For this reason, it was decided to assign "unclear risk of bias "and

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"high" risk of bias" to these two items in our assessment, which was in line with Cochrane Risk of Bias tool. But based on the suggestion of the letter to the editor's authors regarding their citation to the study protocol (Aghajani et al, 2019) and conducting the clinical trial accordingly, risk of bias was reassessed based on the study protocol and as a consequence "unclear risk of bias" and "high risk of bias" for two items of random sequence generation and allocation concealment was replaced by "low risk of bias".

In relation to the assignment of "unclear" risk of bias for two items of both blinding of participants and personnel as well as blinding of outcome assessors, it should be noted that both in the original article (Aghajani et al, 2021) and the study protocol (Aghajani et al, 2019), the respected researchers only reported the blindness of the researchers and outcome assessors responsible for analyzing data from semen samples, endocrine tests, and biomarker analysis, but they have not provided any explanation regarding the blindness of the participants in the study. So "unclear risk of bias" was corrected as "low risk of bias" for the item of outcome assessors. However, for the item of blinding of participants "unclear risk of bias" was considered.

With respect to the study by Pilehvari et al. 2024 (4), the assignment of "low risk of bias" in the item of allocation concealment ""was changed to "unclear risk of bias".

All these corrections were made in table 1 and 2, figure 1 and 2 as well as last paragraph of the "Results" section and the published systematic review (Asghari et al., 2024) was updated.

References

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