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Letter

Gastrointestinal AEs seen in the POP trial due to SOD mimetic activity of calmangafodipir? – Authors' reply

James W. Dear

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The POP Trial Investigators read with interest this letter from Dr. Karlsson [1] regarding the results of our Phase 1 trial [2]. We agree that all safety information from this trial is important for our planning of future trials.

The frequency of gastrointestinal adverse events and serious adverse events in the 4 different treatment groups is already presented in Supplementary Table 2 [2]. These adverse events were nausea, vomiting or abdominal pain – all symptoms that are common after a paracetamol overdose treated with acetylcysteine.

No patient in this trial developed diarrhoea.

References

[1] Karlsson JOG. Gastrointestinal AEs seen in the POP trial due to SOD mimetic activity of calmangafodipir? EBioMedicine 2019 https://www.ebiomedicine.com/article/S2352-3964(19)30556-0/fulltext.

[2] Morrison EE, Oatey K, Gallagher B, et al. Principal results of a randomised open label exploratory, safety and tolerability study with calmangafodipir in patients treated with a 12h regimen of N-acetylcysteine for paracetamol overdose (POP trial). EBioMedicine 2019;46:423–30. https://doi.org/10.1016/j.ebiom.2019.07.013.

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