EBioMedicine 47 (2019) 28

Contents lists available at ScienceDirect

EBioMedicine

journal homepage: www.ebiomedicine.com

EBioMedicine
Published by THE LANCET

Letter

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

James W. Dear

Pharmacology, Therapeutics and Toxicology Unit, Centre for Cardiovascular Science, Queen's Medical Research Institute, University of Edinburgh, Edinburgh, UK

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.

DOIs of original article: https://doi.org/10.1016/j.ebiom.2019.07.013, https://doi.org/10.1016/j.ebiom.2019.08.038.

E-mail address: james.dear@ed.ac.uk.

https://doi.org/10.1016/j.ebiom.2019.08.039