Reviewer's report

Title: Changes in fibroblast growth factor 23 levels in normophosphatemic patients with chronic kidney disease stage 3 treated with lanthanum carbonate: results of the PREFECT study, a phase 2a, double blind, randomized, placebo-controlled trial

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Reviewer: Jessica Kendrick

Reviewer's report:

This is a very interesting study examining the effect of lanthanum carbonate on FGF23 levels in patients with CKD stage 3. The study is limited by its small sample size. Overall it was a negative study as FGF23 levels did not decrease but phosphate excretion did decrease.

Major comments:

1. If the main study endpoint was iFGF23 levels then why were C-terminal (cFGF23) levels used for study inclusion? In their tertiary endpoint cFGF23 levels were reduced compared to placebo. These may be different so I would like the authors to comment on why they chose cFGF23 for inclusion.

2. What is their power calculation based on? i.e. where did they get the 40% reduction in FGF23 levels they were expecting to see? This is a large reduction in FGF23 and it is likely the study was underpowered to show a difference in FGF23 levels from placebo with such small numbers of patients.

3. The authors did not give information on compliance in the study? Did participants tolerate and take the lanthanum carbonate? This has been an issue with previous studies.

4. Not having information on dietary phosphorus intake is a significant limitation to the study. The authors do note this in the discussion.

5. The results are somewhat conflicting with a previous study examining lanthanum carbonate in patients with CKD stage 3 as the previous study found a decrease in FGF23 levels. Although the present study did find a decrease in cFGF23 levels. Again, I am not sure why cFGF23 levels were not the main outcome given that they used cFGF23 levels to determine eligibility. The authors need to comment on this.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

I declare that I have no competing interests