

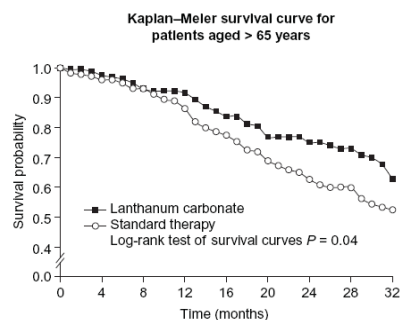
ASSESSMENT OF MORTALITY IN A 2-YEAR COMPARATIVE STUDY OF LANTHANUM CARBONATE VS. STANDARD THERAPY

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Few studies have comprehensively evaluated the survival benefit associated with use of phosphate binders in CKD. Lanthanum carbonate (LC, Shire Pharmaceuticals) is an effective non-calcium, non-resin phosphate binder for the control of hyperphosphatemia in CKD Stage 5. Prospective outcomes studies have not yet been undertaken with LC; however, following regulatory authority discussions, a *post-hoc* survival analysis was performed.

This involved patients enrolled in a Phase 3, 2-year comparative safety study (1:1 randomization) of LC vs. standard therapy (Stx). As patients were treated to target, serum phosphate levels were similar between treatment groups. Survival status, including off-study follow-up, was available for 97% of patients.

At follow-up (mean 23.7 vs. 23.9 months), 20% (135/680) vs. 23% (157/674) of patients had died in the LC and Stx groups, respectively; the difference was not significant (Log rank $P = 0.18$). A subgroup analysis of patients aged > 65 years showed a statistically significant difference in mortality between LC and Stx groups (27% [44/163] vs. 39% [68/173], $P = 0.04$).



Overall mortality was marginally lower in the LC group and there was a significant survival benefit in patients aged > 65 years, the group likely to carry the greatest burden of vascular calcification. These results are similar to those seen in the Dialysis Clinical Outcomes Revisited study, a prospective trial planned to assess survival in patients with CKD.