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Updated Evidence for Sucroferric Oxyhydroxide in Dialysis Patients: Meta-Analysis of Dual Metabolic Benefits and Population-Specific Efficacy Differences

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ADMINISTRATIVE INFORMATION

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Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 July 2026 and was last updated on 12 July 2026.

INTRODUCTION

Review question / Objective Population: Adult patients (aged ≥18 years) with end-stage renal disease (ESRD) receiving maintenance dialysis, including hemodialysis and peritoneal dialysis, complicated with hyperphosphatemia.
Intervention: Treatment with sucroferric oxyhydroxide (SFOH, PA21) at clinically approved doses for hyperphosphatemia management.
Comparison: Control interventions included conventional phosphate binders (sevelamer, lanthanum carbonate, calcium-based phosphate binders) or placebo.
Outcomes: Primary outcomes: Changes in serum phosphorus and hemoglobin levels.Secondary outcomes: Alterations in iron metabolism parameters (transferrin saturation, serum ferritin, serum iron), mineral bone markers, inflammatory indicators, uremic toxins, dialysis adequacy, and all reported adverse events.

Study design: Published and unpublished randomized controlled trials (RCTs) focusing on the efficacy and safety of SFOH in dialysis patients, with no restriction on language or publication time.

Condition being studied This study focused on adult patients aged ≥18 years diagnosed with end-stage renal disease (ESRD) undergoing maintenance hemodialysis or peritoneal dialysis. ESRD patients frequently develop hyperphosphatemia, a common metabolic complication that accelerates vascular calcification, mineral bone disorder, and increases cardiovascular mortality. The target population consisted of dialysis patients with hyperphosphatemia requiring phosphate-lowering treatment.

METHODS

Participant or population Adult patients (aged ≥18 years) with end-stage renal disease (ESRD) receiving maintenance dialysis, including

hemodialysis and peritoneal dialysis, complicated with hyperphosphatemia.

Intervention Treatment with sucroferric oxyhydroxide (SFOH, PA21) at clinically approved doses for hyperphosphatemia management.

Comparator Control interventions included conventional phosphate binders (sevelamer, lanthanum carbonate, calcium-based phosphate binders) or placebo.

Study designs to be included Published and unpublished randomized controlled trials (RCTs) focusing on the efficacy and safety of SFOH in dialysis patients, with no restriction on language or publication time.

Eligibility criteria The following inclusion criteria were used: (1) the study type was a randomized controlled trial (RCT), (2) the patiens (>18 years of age) were receiving kidney replacement therapy (KRT), both modalities, hemodialysis, and peritoneal dialysis, (3) articles published in English or Chinese language. The exclusion criteria were as follows: (1) it was not possible to extract data from the published results, (2) studies that were retrospective cohort studies, (3) the studies contained republished data, (4) studies with patients < 18 years of age, (5) publications are editorials, comments, letters, review articles.

Information sources Two reviewers independently extracted the data from the same set of publications. The following information was extracted: author, nation, year of publication, sample size, average age, intervening measure, proportion of males, observation indicators and follow-up time.

Main outcome(s) The research results included the following: (1) primary outcome: hemoglobin (HB), serum phosphorus (SP) (2) secondary outcomes: calcium (Ca), c-reactive protein (Crp), serum intact- parathyroid hormone (iPTH), indoxyl sulfate (IS), Kt/V urea clearance, p-cresyl sulfate (PCS), serum iron (SI), serum ferritin (SF), transferrin saturation (TSAT) and adverse events (AEs).

Quality assessment / Risk of bias analysis The quality of all trials was independently evaluated by two authors according to the Cochrane quality criteria . An overall risk of bias assessment was also performed by each reviewer . Any disagreements between the authors were settled by discussion with a third author. A weighted kappa value was calculated and used to assess the agreement between the reviewers for the overall risk of bias assessment. Publication bias was evaluated using Begg's plots, Egger's tests and funnel plots.

Strategy of data synthesis STATA 16.0 (Stata Corp LP, College Station, TX, USA) was used to perform the statistical analyses. Meta-regression were used for intuitive assessment of heterogeneity. For the remaining studies, a random effect model was used to pool the effect sizes to calculate the statistical heterogeneity. Heterogeneity was analyzed using I2 and $\chi 2$ statistics. If there was significant heterogeneity, a Galbraith plot was generated to evaluate the consistency and quality of the results. Sensitivity analysis, subgroup analysis and meta-regression were performed to determine sources of heterogeneity.

Subgroup analysis Sensitivity analysis, subgroup analysis and meta-regression were performed to determine sources of heterogeneity.Subgroup analyses stratified by continent were implemented to explore potential drivers of inter-study heterogeneity.

Sensitivity analysis Sensitivity analysis, subgroup analysis and meta-regression were performed to determine sources of heterogeneity.

Country(ies) involved China.

Keywords sucroferric oxyhydroxide; hyperphosphatemia; dialysis; end-stage renal disease; iron metabolism; renal anemia; meta-analysis.

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