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Finerenone in Kidney Transplant Recipients: A Systematic Review and Meta-analysis (Protocol)

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ADMINISTRATIVE INFORMATION

Support - This review receives no external funding or institutional support.

Review stage at the time of initial registration - The review has not yet started.

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 19 November 2026 and was last updated on 19 November 2026.

INTRODUCTION

Review question / Objective In adult kidney transplant recipients, what are the effects of finerenone on proteinuria, albuminuria, kidney allograft function and hyperkalemia compared with placebo, usual care without finerenone or an active comparator? What safety and tolerability outcomes have been reported in finerenone-treated cohorts?

Rationale Clinical evidence on finerenone in kidney transplant recipients includes small observational studies. The magnitude and durability of its effects on urinary protein excretion and the risk of hyperkalemia remain uncertain. A previous systematic review (PROSPERO CRD42024546090) evaluated mineralocorticoid receptor antagonists as a class in randomized trials. This review focuses on finerenone in kidney transplant recipients and includes comparative observational evidence and descriptive safety data from uncontrolled studies.

Condition being studied Kidney transplantation in adults, with a focus on proteinuria, albuminuria, kidney allograft function and hyperkalemia during finerenone treatment. The review includes adult kidney transplant recipients regardless of diabetes status or baseline proteinuria.

METHODS

Search strategy Search PubMed/MEDLINE, Embase, Cochrane CENTRAL and Web of Science Core Collection from inception, with no date or language limits. Update before final synthesis. Pilot PubMed query and adapt for other databases:

(finerenone[tiab] OR Kerendia[tiab] OR "BAY 94-8862"[tiab] OR "BAY 94 8862"[tiab] OR "BAY94-8862"[tiab] OR "BAY948862"[tiab]) AND ("Kidney Transplantation"[Mesh] OR ((kidney[tiab] OR renal[tiab]) AND (transplant*[tiab] OR allograft*[tiab]))).

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Participant or population Adults aged 18 years or older who have received a kidney transplant, irrespective of diabetes status, baseline proteinuria, donor type or time since transplantation. Mixed populations are eligible if results for adult kidney transplant recipients can be extracted separately.

Intervention Finerenone (Kerendia, BAY 94-8862) administered after kidney transplantation at any dose or duration. Record concomitant renin–angiotensin system inhibitors, SGLT2 inhibitors and immunosuppression. For comparative effects, the contribution of finerenone must be distinguishable from systematically different co-interventions.

Comparator Placebo, usual care or no finerenone, or an active comparator. Summarize each comparator category separately. Uncontrolled studies may inform descriptive safety and treatment-response summaries.

Study designs to be included Randomized and non-randomized controlled trials and comparative prospective or retrospective cohorts for intervention effects. Uncontrolled interventional or cohort studies and consecutively enrolled case series for descriptive reporting only.

Eligibility criteria Any healthcare setting, country, publication date or language. Consider dissertations, preprints, registry results and conference abstracts when eligibility and outcome data can be verified. Link multiple reports of the same study. Exclude individual case reports, non-consecutive case series, animal studies, reviews and protocols without results. Record ongoing studies separately.

Information sources PubMed/MEDLINE, Embase, Cochrane CENTRAL, Web of Science Core Collection, ClinicalTrials.gov, and the WHO International Clinical Trials Registry Platform. Search ASN Kidney Week, ERA Congress and American Transplant Congress abstract archives, check references and citing publications, and contact study authors for clarification or missing aggregate data as needed.

Main outcome(s) Proteinuria and albuminuria: change from baseline or between-group differences at follow-up in urinary protein-to-creatinine ratio, 24-hour urinary protein excretion or urinary albumin-to-creatinine ratio, analyzed separately by measure unless valid conversion is possible. Hyperkalemia: number of participants with at least one episode. Extract thresholds and ascertainment windows and group clinically comparable definitions. Report severe hyperkalemia and hyperkalemia leading to discontinuation separately. Prioritize the assessment closest to six months within more than three through six months. Summarize three months or less and more than six months separately. When landmark data are unavailable, report full-study event counts and follow-up duration.

Additional outcome(s) Estimated glomerular filtration rate (eGFR) change and slope, serum creatinine, serum potassium change, acute kidney injury, biopsy-proven acute rejection, graft failure, serious adverse events, treatment discontinuation due to adverse events, and all-cause mortality. Record definitions, units and timing and summarize clinically dissimilar measures separately.

Data management Deduplicate records and link related reports. Two reviewers will independently screen titles, abstracts and full texts and independently extract data using a piloted form. Resolve disagreements by discussion or a third reviewer. Record full-text exclusions and report a PRISMA flow diagram. Collect study design, setting, participant characteristics, time since transplant, baseline eGFR, proteinuria, albuminuria, potassium, diabetes, immunosuppression, intervention and comparator details, follow-up, outcome definitions, event counts, denominators, and adjusted estimates and covariates.

Quality assessment / Risk of bias analysis Two reviewers independently assess risk of bias, resolving disagreements by discussion or a third reviewer. Use Cochrane RoB 2 for randomized trials, ROBINS-I for comparative non-randomized studies, and applicable JBI checklists for uncontrolled cohorts and case series. Consider baseline proteinuria, eGFR, potassium, diabetes, time since transplantation, background treatments and treatment indication as confounders. Compare prespecified and reported outcomes when protocols or registry records are available. Use GRADE for key comparative findings on proteinuria, albuminuria, hyperkalemia, eGFR and graft failure.

Strategy of data synthesis Group findings by design, comparator, outcome definition and follow-up. Analyze randomized and non-randomized comparative studies separately, prefer adjusted estimates in non-randomized comparisons, and describe uncontrolled findings with event counts and denominators. Report risk ratios, mean

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differences, ratios of geometric means or hazard ratios as appropriate with 95% confidence intervals. Pool at least two clinically comparable studies with usable estimates and variances using random-effects restricted maximum likelihood and Hartung–Knapp confidence intervals safeguarded against intervals narrower than conventional random-effects intervals. Report I^2 and tau^2 when estimable. Exclude critical-risk-of-bias studies from pools. Summarize effects and uncertainty in structured tables and text when pooling is unsuitable. Consider funnel plots when at least 10 sufficiently comparable studies contribute to a meta-analysis.

Subgroup analysis If sufficient data are available, explore effect variation by diabetes status and baseline eGFR. Interpret subgroup findings cautiously in light of their precision and the number of studies.

Sensitivity analysis If sufficient studies contribute, reassess pooled findings after excluding studies at high or serious risk of bias and after excluding studies available only as abstracts.

Language restriction No language restrictions.

Country(ies) involved Taiwan.

Other relevant information The review has not yet started at the time of registration. Author contributions describe the planned allocation of responsibilities.

Keywords finerenone; kidney transplantation; proteinuria; albuminuria; hyperkalemia; mineralocorticoid receptor antagonists.

Contributions of each author

Author 1 - Chia-Wei Chang - Chia-Wei Chang will lead protocol development, design and perform searches, independently screen studies and extract data, assess risk of bias, conduct the statistical analyses, and draft the manuscript.
Author 2 - Yih-Ting Chen - Yih-Ting Chen will contribute to protocol development, independently screen studies and extract data, assess risk of bias, verify extracted data and analyses, and critically revise the manuscript.
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Author 3 - Chiao-Yin Sun - Chiao-Yin Sun will supervise the review, provide clinical and methodological guidance, adjudicate reviewer disagreements, critically revise the manuscript, and serve as corresponding author.
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