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VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology

in collaboration with

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Effect of finerenone on eGFR slope across different levels of baseline albuminuria and eGFR: Insights from FINEARTS-HF

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FINEARTS-HF
FINerenone trial to investigate Efficacy and sAfety superioR to placebo in paTientS with Heart Failure

Background

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- Finerenone reduces the risk of kidney disease progression and slows the decline in eGFR among patients with type 2 diabetes (T2DM), chronic kidney disease (CKD), and albuminuria.
- Finerenone did not modify the risk of kidney outcomes or eGFR decline among patients with heart failure (HF) in the FINEARTS-HF trial, who were generally at low risk for kidney disease progression.
- Whether the effect of finerenone on eGFR slope among patients with HF differs according to baseline urine albumin:creatinine ratio (UACR) or eGFR is not clear.

1.Bakris GL et a; *New Engl J Med*. 2020;383:2219–2229; 2. Solomon SD et al *N Engl J Med*. 2024; 3. Mc Causland et al *JACC*, 2024

FINEARTS-HF Study Design

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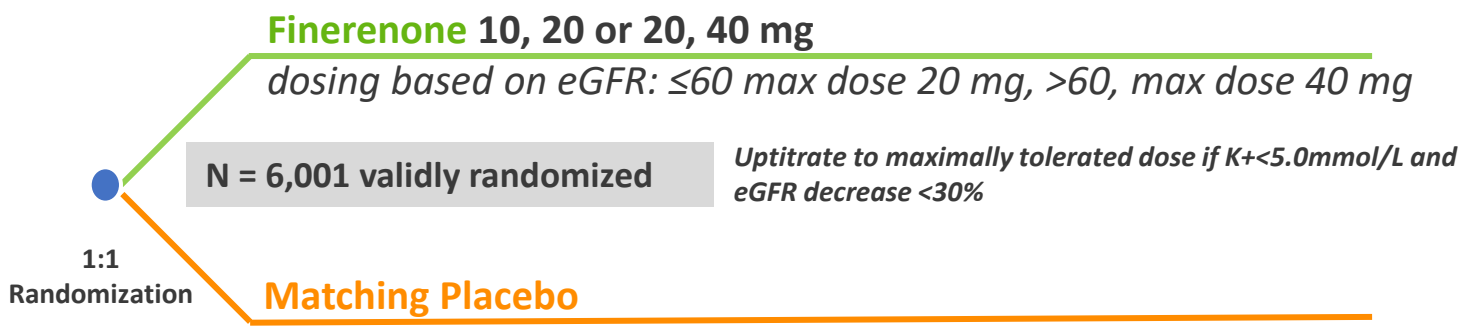
Randomized, double-blind, placebo-controlled trial of patients with HFmrEF/HFpEF

Key Inclusion Criteria

- **Symptomatic HF with LVEF ≥ 40%**
- **Age ≥40 yrs**
- **Elevated natriuretic peptide levels**
- **Structural heart disease (LA↑ or LVH)**
- **Diuretics in the 30d prior to randomization**

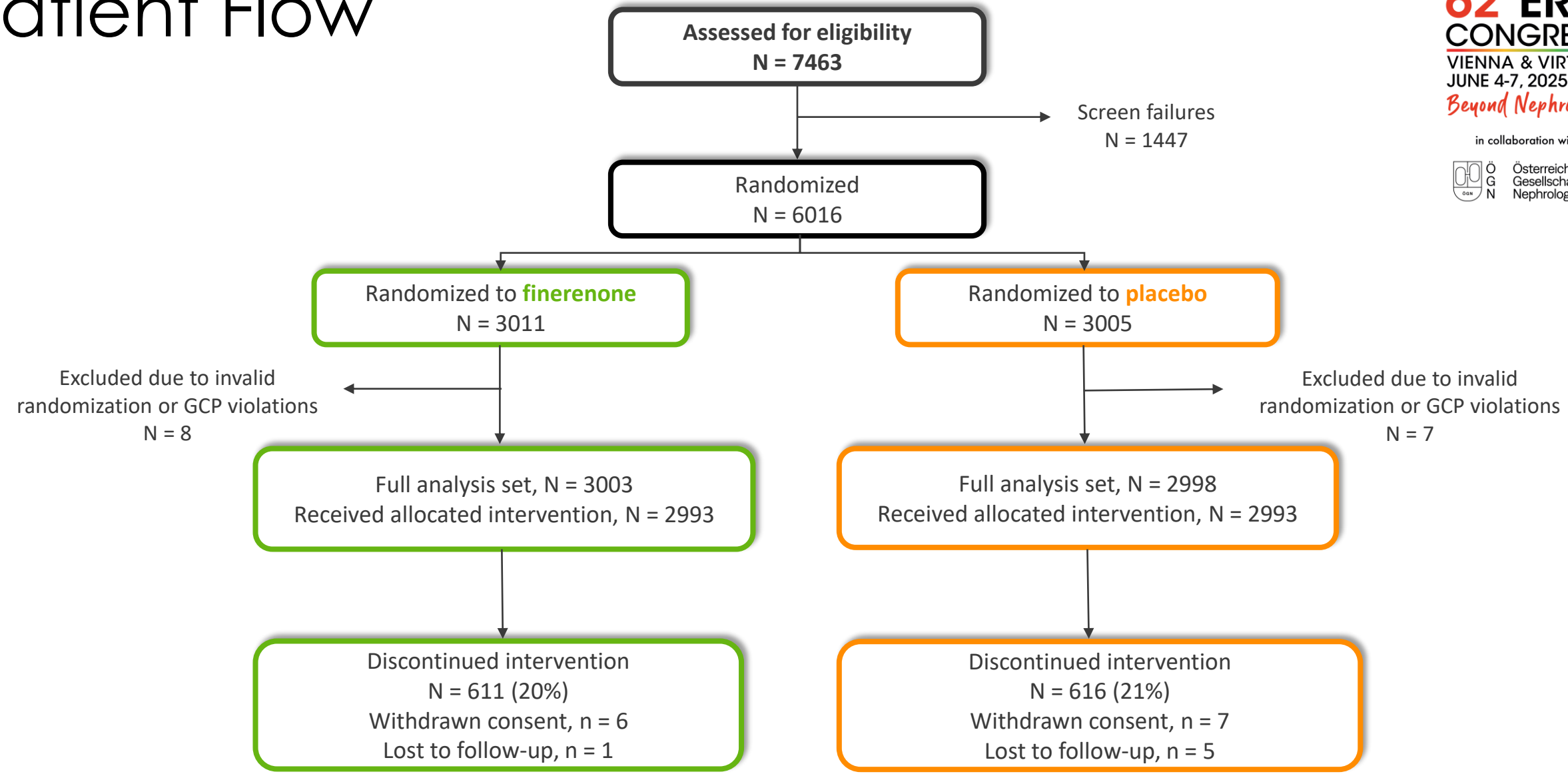
Key Exclusion Criteria

- **eGFR <25 mL/min/1.73 m²**
- **Potassium >5.0 mmol/L**
- **Symptomatic hypotension**
- **MRA use 30d prior to randomization**



Visits: Month 1, then 3-monthly for first 12 months, 4-monthly visits thereafter

Patient Flow



GCP, good clinical practice

UACR and eGFR measurements

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Exposures – UACR and eGFR

- UACR was measured from spot urine collections at baseline in 5,797 participants.
  - Categories: <30 mg/g, 30 to <300 mg/g, and ≥300 mg/g.
- eGFR was calculated using the CKD-EPI 2009 equation
  - Categories: <45, 45 to <60, and ≥60 mL/min/1.73 m^2.

Outcome – eGFR slope

- The changes in eGFR from baseline (prespecified exploratory endpoint)
  - Total slope [baseline to end of study]
  - Acute slope [baseline to 3 months]
  - Chronic slope [3 months to end of study]

Analytic Approach

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- Changes in eGFR (continuous) over time were assessed with repeated measures mixed-effect models, using available data from central laboratory measurements.
- Models were adjusted for treatment assignment, trial visit, geographic region, left ventricular ejection fraction (<60 or ≥60%), the interaction between treatment assignment and visit.
- Intercepts and slopes over time were allowed to vary randomly between patients via the inclusion of patient and time as random effects.
- A two-slope model with a specified change-point at Month 3 was used to estimate the acute slope (Month 0 to Month 3) and the chronic slope (Month 3 to end of study), with the total slope calculated at year 3 as a linear combination of the acute and chronic slope estimates.
- Interaction terms were introduced to explore for differential treatment effects on eGFR slope according to categories of baseline UACR and categories of baseline eGFR.

Baseline Characteristics

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Categories of UACR

	UACR <30 mg/g	UACR 30 - <300 mg/g	UACR ≥300 mg/g
	n=3511	n=1712	n=574
Age, years	71 ± 10	73 ± 9	70 ± 10
Female, n(%)	1625 (46.3%)	785 (45.9%)	220 (38.3%)
SBP, mmHg	128 ± 15	131 ± 15	136 ± 16
eGFR, mL/min/1.73 m2	65 ± 19	60 ± 20	54 ± 20
UACR, mg/g	8 [4, 15]	69 [43, 126]	728 [434, 1463]
LVEF, (%)	53 ± 8	53 ± 8	52 ± 8
NT-proBNP, pg/mL	817 [371, 1529]	1416 [650, 2522]	1661 [758, 3045]
Hx. of Diabetes, n(%)	1133 (32.3%)	826 (48.2%)	396 (69.0%)
ACE inhibitor, n(%)	1342 (38.2%)	552 (32.2%)	181 (31.5%)
ARB, n(%)	1199 (34.1%)	634 (37.0%)	215 (37.5%)
ARNI, n(%)	276 (7.9 %)	169 (9.9 %)	55 (9.6 %)
SGLT2 inhibitor, n(%)	382 (10.9%)	289 (16.9%)	117 (20.4%)
Loop diuretic, n(%)	2988 (85.1%)	1529 (89.3%)	534 (93.0%)
Thiazide, n(%)	511 (14.6%)	225 (13.1%)	75 (13.1%)
Randomized to finerenone, n(%)	1765 (50.3%)	844 (49.3%)	292 (50.9%)

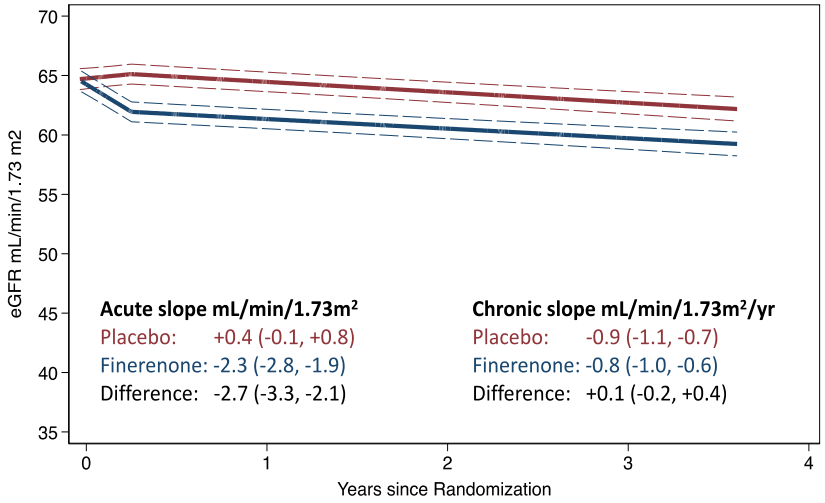
Categories of eGFR

	eGFR ≥60 mL/min/1.73 m²	eGFR 45-<60 mL/min/1.73 m²	eGFR <45 mL/min/1.73 m²
	n=3012	n=1520	n=1265
Age, years	68 ± 10	74 ± 8	77 ± 8
Female, n(%)	1238 (41.1%)	753 (49.5%)	639 (50.5%)
SBP, mmHg	130 ± 15	129 ± 16	129 ± 16
eGFR, mL/min/1.73 m2	78 ± 12	53 ± 4	36 ± 6
UACR, mg/g	14 [6, 45]	20 [8, 76]	33 [11, 160]
LVEF, (%)	52 ± 8	53 ± 8	53 ± 8
NT-proBNP, pg/mL	798 [356, 1497]	1183 [534, 2098]	1593 [770, 2972]
Hx. of Diabetes, n(%)	1099 (36.5%)	625 (41.1%)	631 (49.9%)
ACE inhibitor, n(%)	1182 (39.2%)	516 (33.9%)	377 (29.8%)
ARB, n(%)	996 (33.1%)	593 (39.0%)	459 (36.3%)
ARNI, n(%)	291 (9.7 %)	114 (7.5 %)	95 (7.5 %)
SGLT2 inhibitor, n(%)	360 (12.0%)	213 (14.0%)	215 (17.0%)
Loop diuretic, n(%)	2565 (85.2%)	1315 (86.5%)	1171 (92.6%)
Thiazide, n(%)	445 (14.8%)	234 (15.4%)	132 (10.4%)
Randomized to finerenone, n(%)	1503 (49.9%)	777 (51.1%)	621 (49.1%)

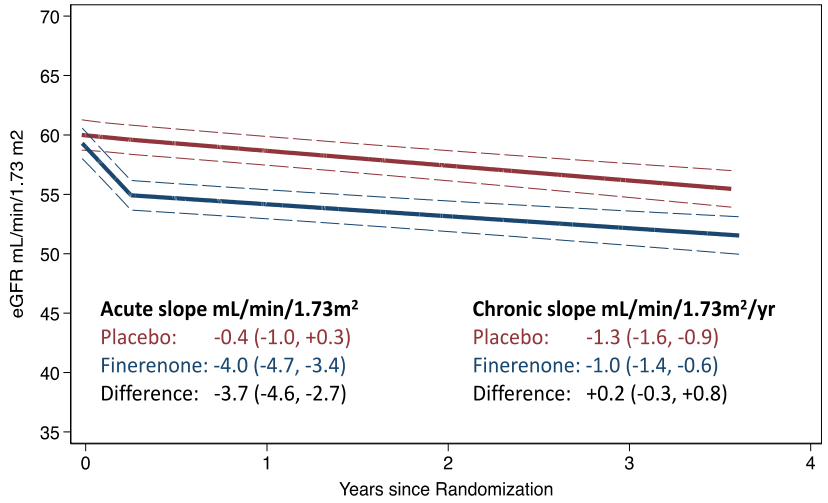
Results: Categories of UACR

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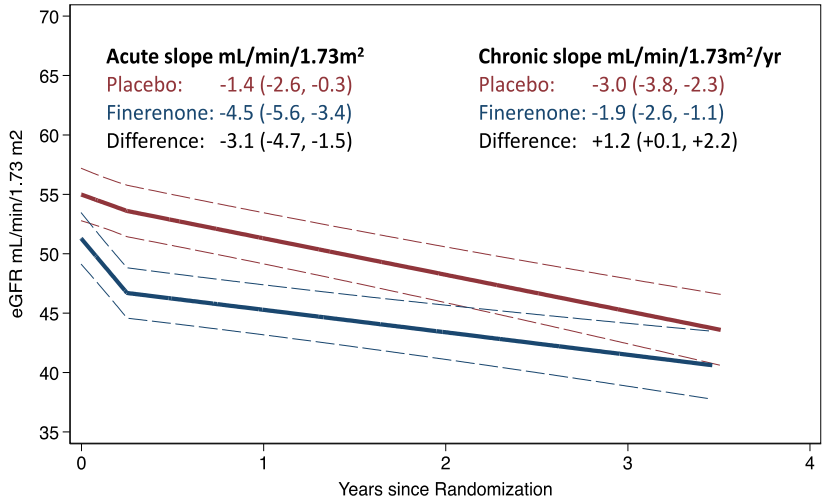
UACR <30 mg/g; n=3,511



UACR 30 to <300 mg/g; n=1,712



UACR ≥300 mg/g; n=574

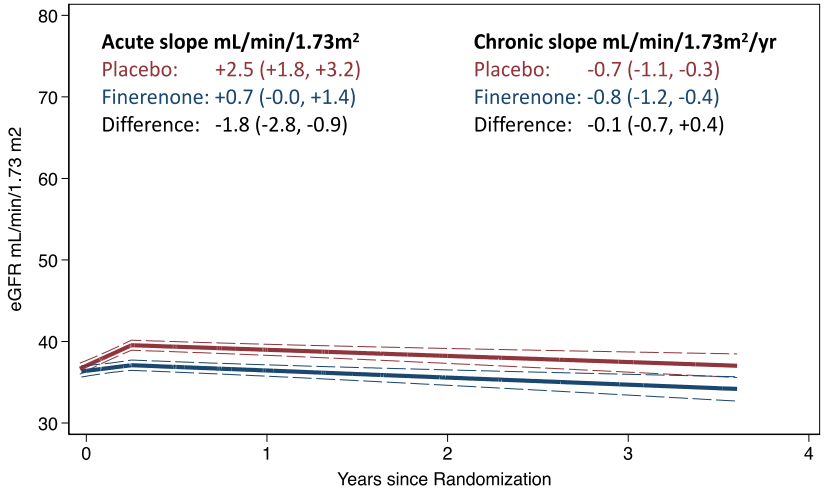


P-interaction=0.09

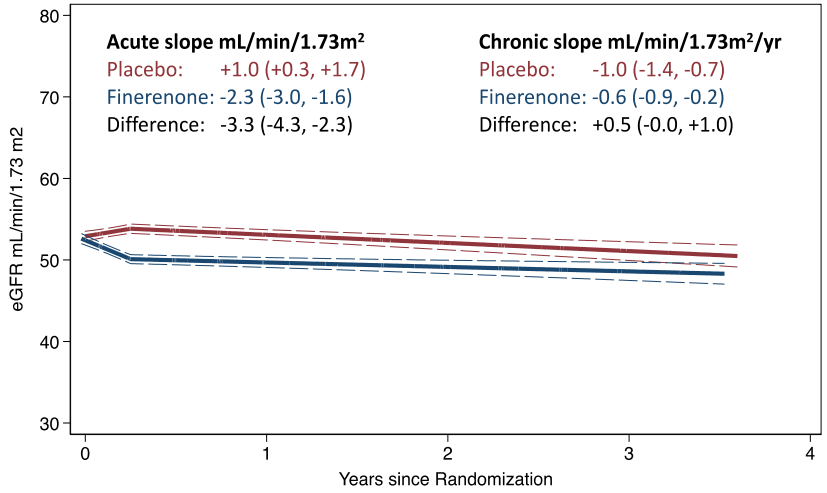
Results: Categories of eGFR

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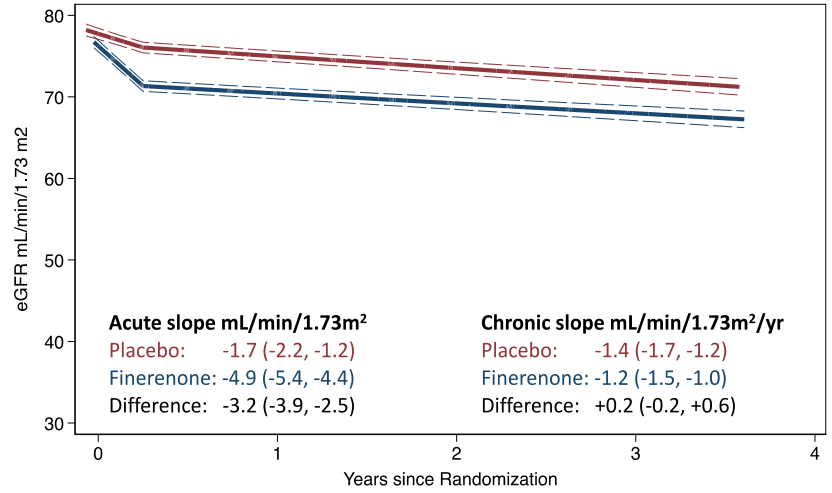
eGFR <45 mL/min/1.73 m²; n=1,332



eGFR 45 to <60 mL/min/1.73 m²; n=1,556



eGFR ≥60 mL/min/1.73 m²; n=3,113



P-interaction=0.48

Conclusions

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- Finerenone appears to slow eGFR decline relative to placebo to a clinically meaningful degree among patients with higher baseline UACR
- There was no suggestion of heterogeneity according to categories of baseline eGFR
- Overall, consistent with data from FIDELITY, the present data support the current practice for including higher UACR (over lower eGFR) as an enrichment criterion for trials examining treatment effects on eGFR slope

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