62nd ERA CONGRESS
VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology

in collaboration with

Österreichische Gesellschaft für Nephrologie

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

Finnian R. Mc Causland[1]*; Hiddo J. L. Heerspink[2]*; Muthiah Vaduganathan[1]; Brian L. Claggett[1]; Akshay S. Desai[1]; Pardeep S. Jhund[3]; Martina M. McGrath[1]; Katja Rohwedder[4]; Flaviana Amarante[4]; Meike Brinker[4]; Patrick Schloemer[4]; Carolyn SP Lam[5]; Michele Senni[6]; Sanjiv J. Shah[7]; Adriaan A. Voors[8]; Faiez Zannad[9]; Bertram Pitt[10]; John JV McMurray[3]; Scott D. Solomon[1]

[1]Brigham & Women's Hospital, Harvard Medical School, Boston, Massachusetts, United States; [2]Department of Clinical Pharmacy and Pharmacology, University of Groningen, University Medical Center Groningen, Groningen, The Netherlands; [3]University of Glasgow, Glasgow, Scotland, United Kingdom; [4]Bayer, Germany/US; [5]National Heart Centre Singapore & Duke-National University of Singapore, Singapore; [6]University of Milano-Bicocca ASST Papa Giovanni XXIII Hospital, Bergamo, Italy; [7]Northwestern University Feinberg School of Medicine, Chicago, Illinois, United States; [8]University of Groningen, Groningen, Netherlands; [9]University of Lorraine, Nancy, France; [10]University of Michigan, Ann Arbor, Michigan, United States

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

Background

62nd ERA CONGRESS
VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology
in collaboration with
ÖGN Österreichische Gesellschaft für Nephrologie

- 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

62nd ERA CONGRESS
VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology
in collaboration with
Österreichische Gesellschaft für Nephrologie

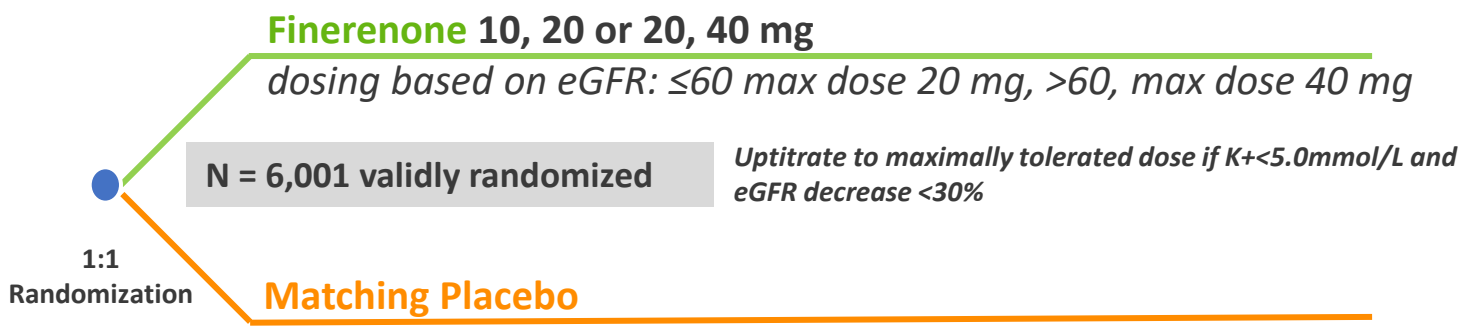
Randomized, double-blind, placebo-controlled trial of patients with HFmrEF/HFpEF

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**

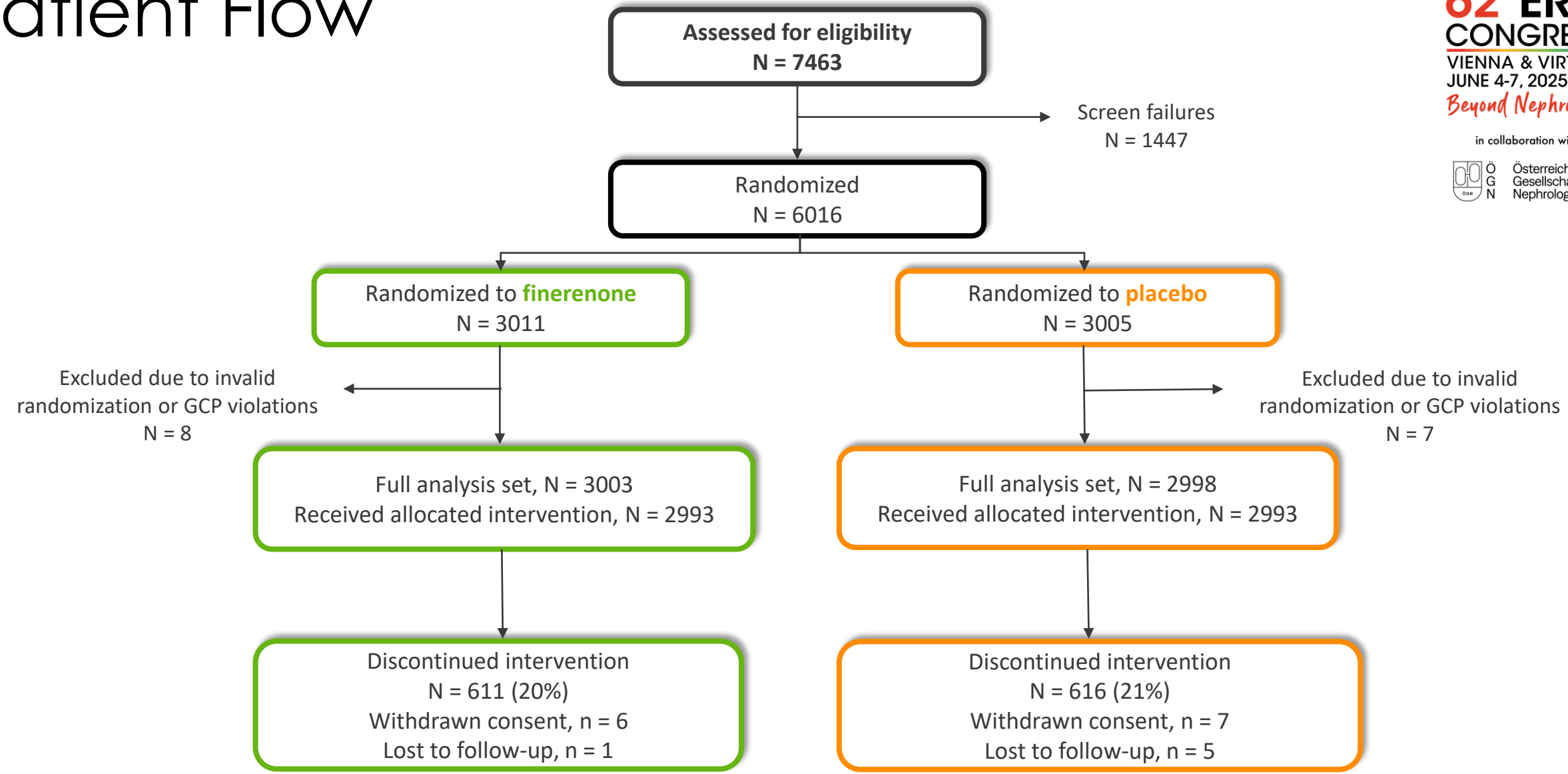
Key Exclusion Criteria

- **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

62nd ERA CONGRESS
VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology
in collaboration with
ÖGN Österreichische Gesellschaft für Nephrologie

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

62nd ERA CONGRESS
VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology
in collaboration with
ÖGN Österreichische Gesellschaft für Nephrologie

- 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

62nd ERA CONGRESS
VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology
in collaboration with

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%)

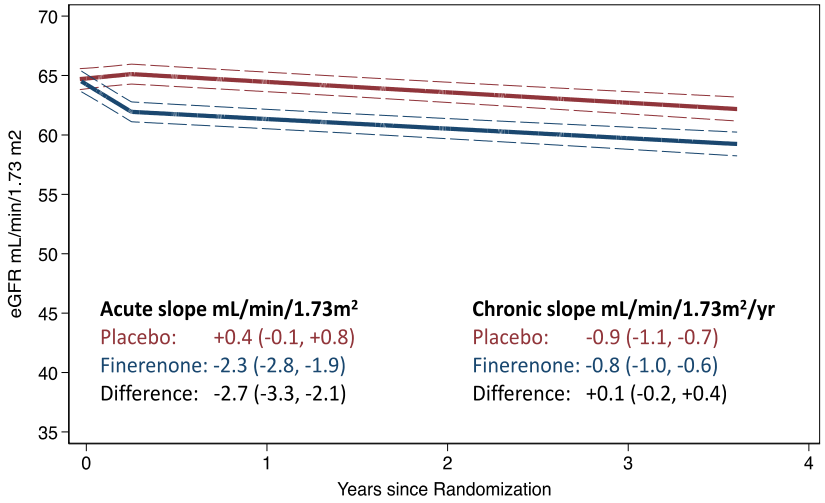
Categories of eGFR

	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%)

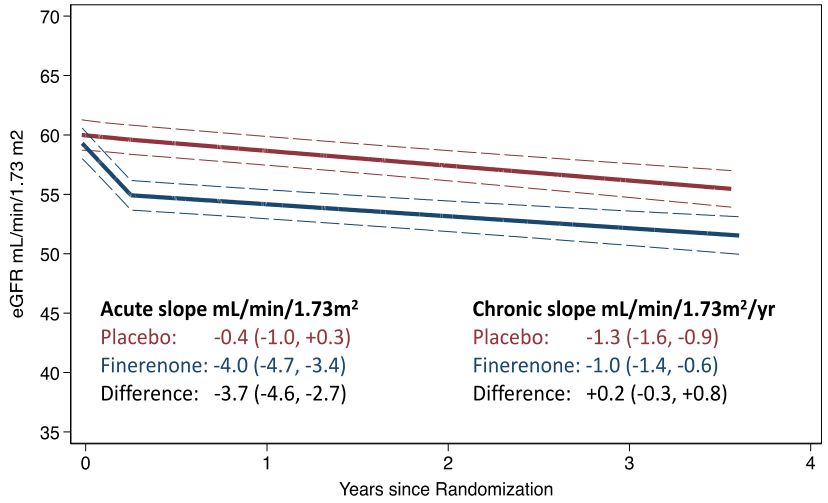
Results: Categories of UACR

62nd ERA CONGRESS
VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology

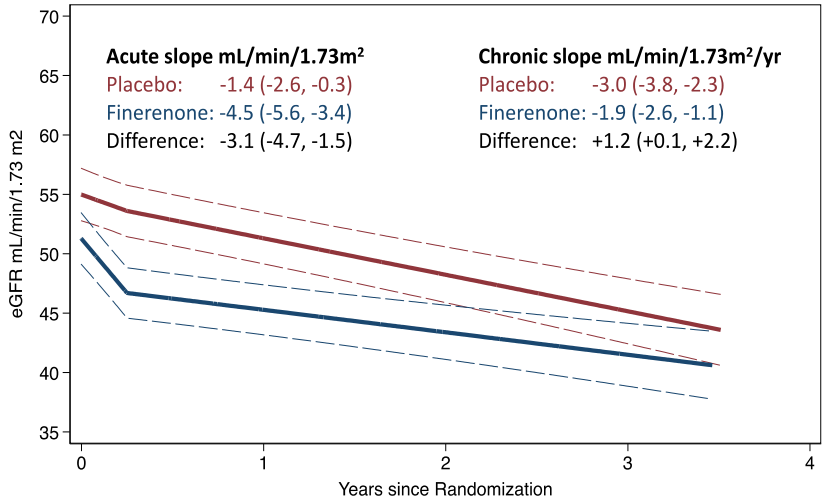
UACR <30 mg/g; n=3,511



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



UACR ≥300 mg/g; n=574

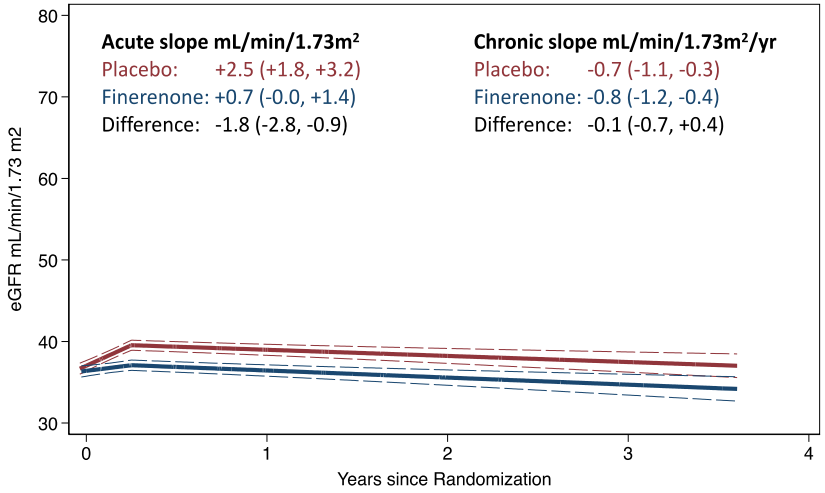


P-interaction=0.09

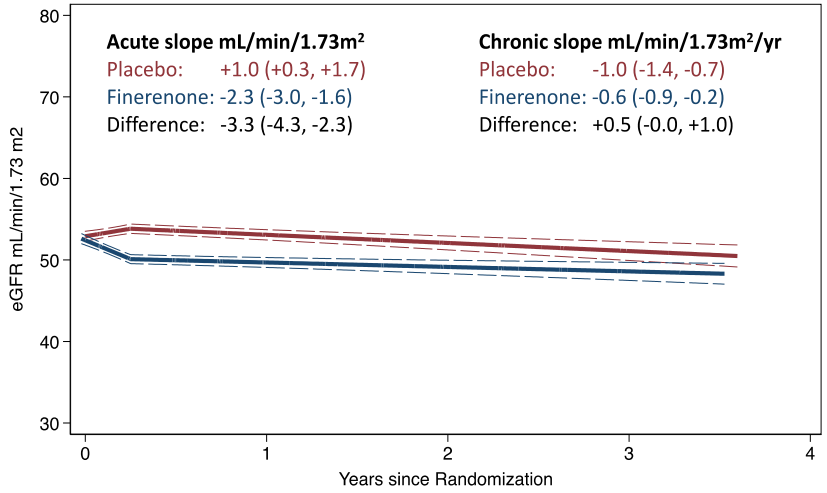
Results: Categories of eGFR

62nd ERA CONGRESS
VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology

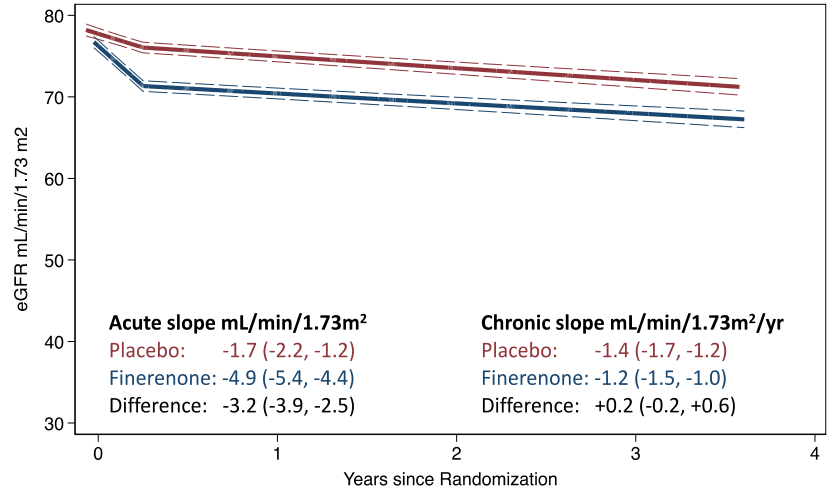
eGFR <45 mL/min/1.73 m²; n=1,332



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

62nd ERA CONGRESS
VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology
in collaboration with
Österreichische Gesellschaft für Nephrologie

- 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

Acknowledgements

62nd ERA CONGRESS
VIENNA & VIRTUAL
JUNE 4-7, 2025
Beyond Nephrology

in collaboration with

Österreichische Gesellschaft für Nephrologie

Steering Committee

Scott D. Solomon, MD & John J.V. McMurray, MD, Co-Chairs

Carolyn S.P. Lam, MD, Bertram Pitt, MD, Michele Senni, MD, Sanjiv Shah, MD,

Adriaan Voors, MD, Faiez Zannad, MD

Sponsor Leadership

Bayer

Prabhakar Viswanathan, MD, Ilse van Gameren, Flaviana Amarante, MD, James Lay-Flurrie, MSc Catherine Salt, Michelle King, Maria Borentain, MD

Clinical Events Committee

Akshay Desai, MD, Pardeep Jhund, MD (Chairs)

Data Safety Monitoring Committee

Aldo Maggioni, MD, Murray Epstein, MD (Chairs)

Independent Statistical Team

Brian Claggett, PhD, Muthiah Vaduganathan, MD, Pardeep Jhund, MD, Alasdair Henderson, PhD

National Lead Investigators

Argentina	Felipe Martinez
Australia	John Atherton
Austria	Dirk von Lewinski
Brazil	Jose Francisco Kerr Saraiva
Bulgaria	Tzvetana Katova
Canada	Shelley Zieroth
Canada	Jay Udell
Canada	Subodh Verma
China	Ma chang-sheng
Colombia	Clara Inés Saldarriaga
Czech Rep	Vojtěch Melenovský
Denmark	Morten Schou
Finland	Heikki Ukkonen
Germany	Johann Bauersachs
Greece	Gerasimos Filippatos
Hungary	Bela Merkely
Hong Kong	Alex Lee
India	Vijay Chopra
Israel	Sorel Goland
Italy	Savina Nodari

Japan	Naoki Sato
Latvia	Gustavs Latkovskis
Malaysia	Imran Zainal Abidin
Mexico	Marco Alcocer-Gamba
Mexico	Guillermo Llamas Esperón
Netherlands	Gerard Linssen
New Zealand	Richard Troughton
Poland	Grzegorz Gajos
Portugal	Cândida Fonseca
Romania	Ovidiu Chioncel
Russia	Vyacheslav Mareev
Slovakia	Eva Goncalvesova
South-Korea	Seokmin Kang
Spain	Josep Comin Colet
Taiwan	Chern-En Chiang
Turkey	Mehmet Birhan Yılmaz
UK	Mark Petrie
Ukraine	Leonid Voronkov
USA	Orly Vardeny
USA	Kavita Sharma
USA	Mikhail Kosiborod

We thank all the FINEARTS-HF Investigators and participants!

ERA LEADING EUROPEAN NEPHROLOGY