

Hyperkalemia Risk with Finerenone: Results from the FIDELIO-DKD Trial

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Table S1. Baseline demographics in patients with versus without any serum potassium concentration >5.5 mmol/L, by treatment group

| Baseline demographics | No serum [K ⁺] >5.5 mmol/L | | Any serum [K ⁺] >5.5 mmol/L | |
|--|--|------------------|---|-----------------|
| | Finerenone (n=2151) | Placebo (n=2453) | Finerenone (n=676) | Placebo (n=378) |
| Sex, male, n (%) | 1507 (70.1) | 1772 (72.2) | 442 (65.4) | 252 (66.7) |
| Age, years, mean ± SD | 65.64±8.95 | 65.96±9.08 | 64.87±8.87 | 63.70±9.44 |
| Age category, n (%) | | | | |
| <65 years | 898 (41.7) | 981 (40.0) | 303 (44.8) | 190 (50.3) |
| 65–74 years | 904 (42.0) | 1056 (43.0) | 291 (43.0) | 143 (37.8) |
| ≥75 years | 349 (16.2) | 416 (17.0) | 82 (12.1) | 45 (11.9) |
| Serum [K ⁺], mmol/L, mean ± SD | 4.29±0.43 | 4.32±0.43 | 4.62±0.45 | 4.70±0.51 |
| Serum [K ⁺], mmol/L, n (%) | | | | |
| ≤4.1 | 770 (35.8) | 807 (32.9) | 88 (13.0) | 43 (11.4) |
| >4.1–≤4.5 | 808 (37.6) | 898 (36.6) | 213 (31.5) | 110 (29.1) |
| >4.5–≤4.8 | 381 (17.7) | 497 (20.3) | 180 (26.6) | 94 (24.9) |
| >4.8–≤5.0 | 107 (5.0) | 140 (5.7) | 84 (12.4) | 48 (12.7) |
| >5.0 | 85 (4.0) | 111 (4.5) | 111 (16.4) | 83 (22.0) |

| | | | | |
|---|----------------------------|----------------------------|----------------------------|-----------------------------|
| eGFR, mL/min/1.73 m ² , mean ± SD | 45.03±12.54 | 44.66±12.34 | 42.22±12.30 | 42.17±13.82 |
| eGFR category, mL/min/1.73 m ² , <i>n</i> (%) | | | | |
| <25 | 48 (2.2) | 54 (2.2) | 18 (2.7) | 15 (4.0) |
| 25–<45 | 1060 (49.3) | 1274 (51.9) | 413 (61.1) | 225 (59.5) |
| 45–<60 | 782 (36.4) | 829 (33.8) | 189 (28.0) | 97 (25.7) |
| ≥60 | 261 (12.1) | 296 (12.1) | 56 (8.3) | 41 (10.8) |
| UACR, mg/g, median (IQR) | 820.42 (437.61–1551.41) | 823.05 (442.76–1578.53) | 866.85 (464.46–1803.19) | 1161.43 (521.39–2236.54) |
| UACR category, mg/g, <i>n</i> (%) | | | | |
| <30 | 8 (0.4) | 10 (0.4) | 3 (0.4) | 2 (0.5) |
| 30–<300 | 255 (11.9) | 292 (11.9) | 94 (13.9) | 43 (11.4) |
| ≥300 | 1887 (87.7) | 2151 (87.7) | 579 (85.7) | 333 (88.1) |
| eGFR 25–<45 mL/min/1.73 m ² and serum [K ⁺] >4.5 mmol/L, <i>n</i> (%) | | | | |
| No | 1847 (85.9) | 2050 (83.6) | 447 (66.1) | 252 (66.7) |
| Yes | 304 (14.1) | 403 (16.4) | 229 (33.9) | 126 (33.3) |
| History of CV disease, <i>n</i> (%) | 986 (45.8) | 1111 (45.3) | 315 (46.6) | 188 (49.7) |

| | | | | |
|---|-------------|-------------|------------|------------|
| Label-recommended dose of RASi, <i>n</i> (%) ^a | | | | |
| ≤ minimum | 648 (30.1) | 720 (29.4) | 218 (32.2) | 113 (29.9) |
| > minimum to < maximum | 501 (23.3) | 624 (25.4) | 161 (23.8) | 102 (27.0) |
| ≥ maximum | 994 (46.2) | 1102 (44.9) | 297 (43.9) | 161 (42.6) |
| Beta-blocker, <i>n</i> (%) | 1101 (51.2) | 1304 (53.2) | 359 (53.1) | 201 (53.2) |
| Diuretic, <i>n</i> (%) | | | | |
| Loop | 610 (28.4) | 728 (29.7) | 176 (26.0) | 99 (26.2) |
| Thiazide | 563 (26.2) | 583 (23.8) | 134 (19.8) | 71 (18.8) |
| Potassium binders, <i>n</i> (%) | 43 (2.0) | 48 (2.0) | 27 (4.0) | 18 (4.8) |
| Potassium supplements, <i>n</i> (%) | 74 (3.4) | 82 (3.3) | 11 (1.6) | 3 (0.8) |
| Glucose-lowering therapies, <i>n</i> (%) | 2080 (96.7) | 2401 (97.9) | 661 (97.8) | 366 (96.8) |
| SGLT-2i | 111 (5.2) | 129 (5.3) | 13 (1.9) | 6 (1.6) |

Percentages are rounded to the nearest decimal place. CV, cardiovascular; eGFR, estimated glomerular filtration rate; IQR, interquartile range; [K⁺], potassium concentration; RASi, renin–angiotensin system inhibitor; SD, standard deviation; SGLT-2i, sodium–glucose co-transporter-2 inhibitor; UACR, urine albumin-to-creatinine ratio.

^aInformation on RASi dosing was missing in 15 patients without any serum [K⁺] >5.5 mmol/L (8 patients in the finerenone group and 7 patients in the placebo group) and 2 patients with any serum [K⁺] >5.5 mmol/L (in the finerenone group).

Table S2. Baseline demographics in patients with versus without any serum potassium concentration >6.0 mmol/L

| Baseline demographics | No serum [K⁺] >6.0 mmol/L (n=5430) | Any serum [K⁺] >6.0 mmol/L (n=228) |
|---|---|---|
| Sex, male, n (%) | 3831 (70.6) | 142 (62.3) |
| Age, years, mean ± SD | 65.64±9.02 | 63.63±9.69 |
| Age category, n (%) | | |
| <65 years | 2262 (41.7) | 110 (48.2) |
| 65–74 years | 2298 (42.3) | 96 (42.1) |
| ≥75 years | 870 (16.0) | 22 (9.6) |
| Serum [K ⁺], mmol/L, mean ± SD | 4.36±0.45 | 4.65±0.57 |
| Serum [K ⁺], mmol/L, n (%) | | |
| ≤4.1 | 1677 (30.9) | 31 (13.6) |
| >4.1–≤4.5 | 1960 (36.1) | 69 (30.3) |
| >4.5–≤4.8 | 1097 (20.2) | 55 (24.1) |
| >4.8–≤5.0 | 350 (6.4) | 29 (12.7) |
| >5.0 | 346 (6.4) | 44 (19.3) |
| eGFR, mL/min/1.73 m ² , mean ± SD | 44.52±12.53 | 40.22±12.58 |
| eGFR category, mL/min/1.73 m ² , n (%) | | |
| <25 | 122 (2.2) | 13 (5.7) |
| 25–<45 | 2826 (52.0) | 146 (64.0) |
| 45–<60 | 1847 (34.0) | 50 (21.9) |
| ≥60 | 635 (11.7) | 19 (8.3) |
| UACR, mg/g, median (IQR) | 839.87 (442.88–1608.10) | 1082.77 (562.93–2072.66) |
| UACR category, mg/g, n (%) | | |
| <30 | 21 (0.4) | 2 (0.9) |

| | | |
|--|-------------|------------|
| 30–<300 | 660 (12.2) | 24 (10.5) |
| ≥300 | 4748 (87.4) | 202 (88.6) |
| eGFR 25–<45 mL/min/1.73 m ² and serum [K ⁺] >4.5 mmol/L, <i>n</i> (%) | | |
| No | 4443 (81.8) | 153 (67.1) |
| Yes | 987 (18.2) | 75 (32.9) |
| Label-recommended dose of RASi, <i>n</i> (%) ^a | | |
| ≤ minimum | 1622 (29.9) | 77 (33.8) |
| > minimum to < maximum | 1334 (24.6) | 54 (23.7) |
| ≥ maximum | 2457 (45.2) | 97 (42.5) |
| Beta-blocker, <i>n</i> (%) | 2855 (52.6) | 110 (48.2) |
| Diuretic, <i>n</i> (%) | 3102 (57.1) | 102 (44.7) |
| Loop | 1560 (28.7) | 53 (23.2) |
| Thiazide | 1310 (24.1) | 41 (18.0) |
| Potassium binders, <i>n</i> (%) | 123 (2.3) | 13 (5.7) |
| Potassium supplements, <i>n</i> (%) | 164 (3.0) | 6 (2.6) |
| Glucose-lowering therapies, <i>n</i> (%) | 5284 (97.3) | 224 (98.2) |
| SGLT-2i | 257 (4.7) | 2 (0.9) |

Percentages are rounded to the nearest decimal place. eGFR, estimated glomerular filtration rate; IQR, interquartile range; [K⁺], potassium concentration; RASi, renin–angiotensin system inhibitor; SD, standard deviation; SGLT-2i, sodium-glucose co-transporter-2 inhibitor; UACR, urine albumin-to-creatinine ratio.

^aInformation on RASi dosing was missing in 17 patients without any serum [K⁺] >6.0 mmol/L.

Table S3. Baseline demographics in patients with versus without any serum potassium concentration >6.0 mmol/L, by treatment group

| Baseline demographics | No serum [K ⁺] >6.0 mmol/L | | Any serum [K ⁺] >6.0 mmol/L | |
|--|--|------------------|---|----------------|
| | Finerenone (n=2680) | Placebo (n=2750) | Finerenone (n=147) | Placebo (n=81) |
| Sex, male, n (%) | 1858 (69.3) | 1973 (71.7) | 91 (61.9) | 51 (63.0) |
| Age, years, mean ± SD | 65.48±8.91 | 65.79±9.12 | 64.90±9.51 | 61.32±9.64 |
| Age category, n (%) | | | | |
| <65 years | 1135 (42.4) | 1127 (41.0) | 66 (44.9) | 44 (54.3) |
| 65–74 years | 1133 (42.3) | 1165 (42.4) | 62 (42.2) | 34 (42.0) |
| ≥75 years | 412 (15.4) | 458 (16.7) | 19 (12.9) | 3 (3.7) |
| Serum [K ⁺], mmol/L, mean ± SD | 4.36±0.45 | 4.36±0.45 | 4.62±0.50 | 4.71±0.69 |
| Serum [K ⁺], mmol/L, n (%) | | | | |
| ≤4.1 | 839 (31.3) | 838 (30.5) | 19 (12.9) | 12 (14.8) |
| >4.1–≤4.5 | 973 (36.3) | 987 (35.9) | 48 (32.7) | 21 (25.9) |
| >4.5–≤4.8 | 526 (19.6) | 571 (20.8) | 35 (23.8) | 20 (24.7) |
| >4.8–≤5.0 | 170 (6.3) | 180 (6.5) | 21 (14.3) | 8 (9.9) |
| >5.0 | 172 (6.4) | 174 (6.3) | 24 (16.3) | 20 (24.7) |
| eGFR, mL/min/1.73 m ² , mean ± SD | 44.62±12.55 | 44.41±12.50 | 39.51±11.19 | 41.51±14.75 |

| | | | | |
|---|----------------------------|----------------------------|-----------------------------|-----------------------------|
| eGFR category, mL/min/1.73 m ² , <i>n</i> (%) | | | | |
| <25 | 57 (2.1) | 65 (2.4) | 9 (6.1) | 4 (4.9) |
| 25–<45 | 1376 (51.3) | 1450 (52.7) | 97 (66.0) | 49 (60.5) |
| 45–<60 | 938 (35.0) | 909 (33.1) | 33 (22.4) | 17 (21.0) |
| ≥60 | 309 (11.5) | 326 (11.9) | 8 (5.4) | 11 (13.6) |
| UACR, mg/g, median (IQR) | 818.57 (438.43–1593.89) | 860.60 (447.76–1617.35) | 1069.76 (558.44–2046.04) | 1255.60 (637.20–2088.09) |
| UACR category, mg/g, <i>n</i> (%) | | | | |
| <30 | 10 (0.4) | 11 (0.4) | 1 (0.7) | 1 (1.2) |
| 30–<300 | 333 (12.4) | 327 (11.9) | 16 (10.9) | 8 (9.9) |
| ≥300 | 2336 (87.2) | 2412 (87.7) | 130 (88.4) | 72 (88.9) |
| eGFR 25–<45 mL/min/1.73 m ² and serum [K ⁺] >4.5 mmol/L, <i>n</i> (%) | | | | |
| No | 2197 (82.0) | 2246 (81.7) | 97 (66.0) | 56 (69.1) |
| Yes | 483 (18.0) | 504 (18.3) | 50 (34.0) | 25 (30.9) |
| History of CV disease, <i>n</i> (%) | 1237 (46.2) | 1257 (45.7) | 64 (43.5) | 42 (51.9) |
| Label-recommended dose of RASi, <i>n</i> (%) ^a | | | | |

| | | | | |
|--|-------------|-------------|------------|-----------|
| ≤ minimum | 815 (30.4) | 807 (29.3) | 51 (34.7) | 26 (32.1) |
| > minimum to < maximum | 628 (23.4) | 706 (25.7) | 34 (23.1) | 20 (24.7) |
| ≥ maximum | 1229 (45.9) | 1228 (44.7) | 62 (42.2) | 35 (43.2) |
| Beta-blocker, <i>n</i> (%) | 1389 (51.8) | 1466 (53.3) | 71 (48.3) | 39 (48.1) |
| Diuretic, <i>n</i> (%) | 1509 (56.3) | 1593 (57.9) | 65 (44.2) | 37 (45.7) |
| Loop | 754 (28.1) | 806 (29.3) | 32 (21.8) | 21 (25.9) |
| Thiazide | 668 (24.9) | 642 (23.3) | 29 (19.7) | 12 (14.8) |
| Potassium binders, <i>n</i> (%) | 63 (2.4) | 60 (2.2) | 7 (4.8) | 6 (7.4) |
| Potassium supplements, <i>n</i> (%) | 81 (3.0) | 83 (3.0) | 4 (2.7) | 2 (2.5) |
| Glucose-lowering therapies, <i>n</i> (%) | 2596 (96.9) | 2688 (97.7) | 145 (98.6) | 79 (97.5) |
| SGLT-2i | 123 (4.6) | 134 (4.9) | 1 (0.7) | 1 (1.2) |

Percentages are rounded to the nearest decimal place. CV, cardiovascular; eGFR, estimated glomerular filtration rate; IQR, interquartile range; [K⁺], potassium concentration; RASi, renin–angiotensin system inhibitor; SD, standard deviation; SGLT-2i, sodium-glucose co-transporter-2 inhibitor; UACR, urine albumin-to-creatinine ratio.

^aInformation on RASi dosing was missing in 17 patients without any serum [K⁺] >6.0 mmol/L (8 patients in the finerenone group and 9 patients in the placebo group).

Table S4. Use of potassium binders at baseline and during the FIDELIO-DKD trial

| | Finerenone (n=2827) | Placebo (n=2831) | Total (N=5558) |
|---|--------------------------------------|-----------------------------------|---------------------------------|
| Patients receiving a potassium binder at baseline, <i>n</i> (%) | 70 (2.5) | 66 (2.3) | 136 (2.4) |
| Calcium polystyrene sulphonate | 51 (1.8) | 40 (1.4) | 91 (1.6) |
| Sodium polystyrene sulphonate | 17 (0.6) | 24 (0.8) | 41 (0.7) |
| Patiromer | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Patients receiving a potassium binder at any point during the trial, <i>n</i> (%) | 307 (10.9) | 183 (6.5) | 490 (8.7) |
| Calcium polystyrene sulphonate | 154 (5.4) | 102 (3.6) | 256 (4.5) |
| Sodium polystyrene sulphonate | 149 (5.3) | 80 (2.8) | 229 (4.0) |
| Patiromer | 18 (0.6) | 9 (0.3) | 27 (0.5) |
| Sodium zirconium cyclosilicate | 9 (0.3) | 5 (0.2) | 14 (0.2) |

FIDELIO-DKD, Finerenone in reducing kidney failure and disease progression in Diabetic Kidney Disease

Supplemental Figures

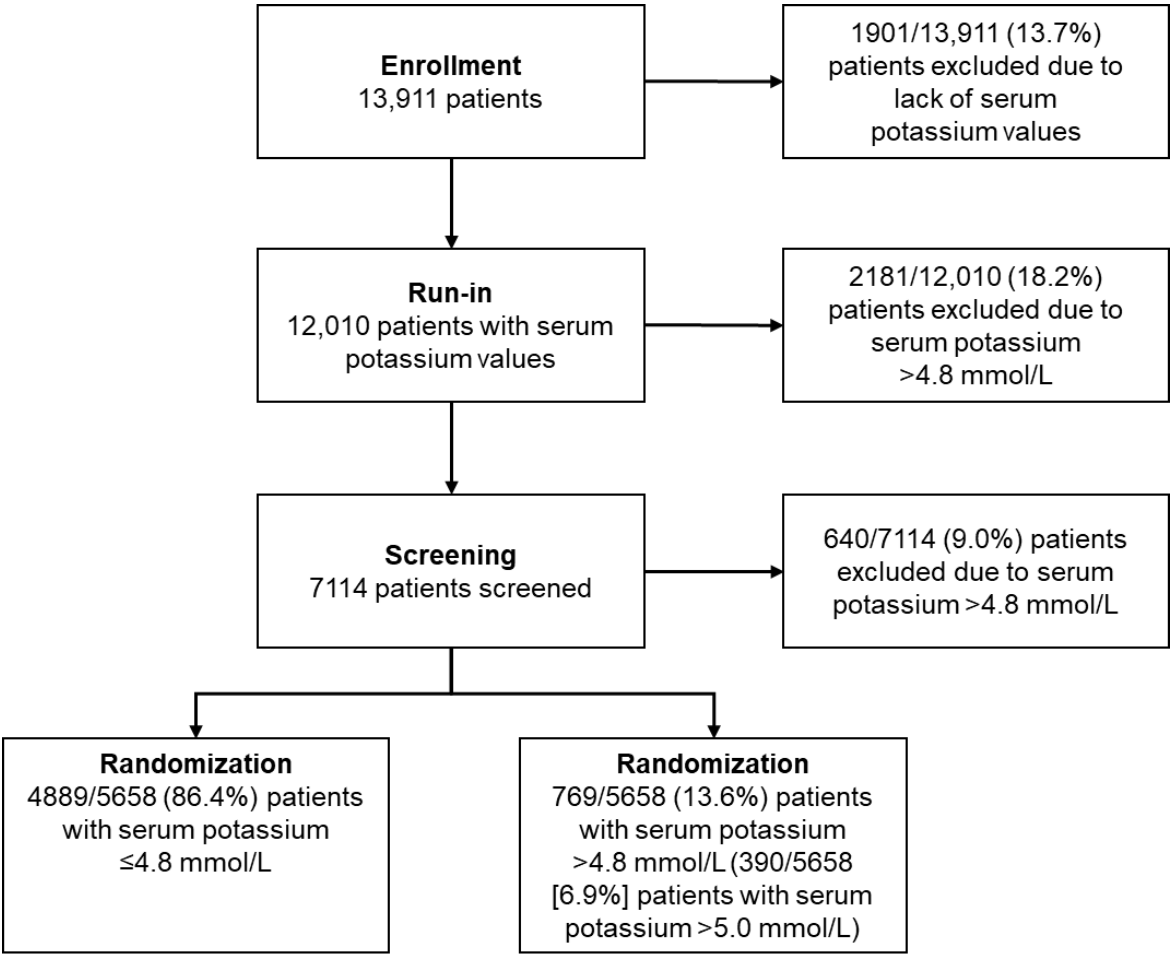


Figure S1. Flow of patients through the study from enrollment to randomization based on inclusion/exclusion related to serum potassium measurements.

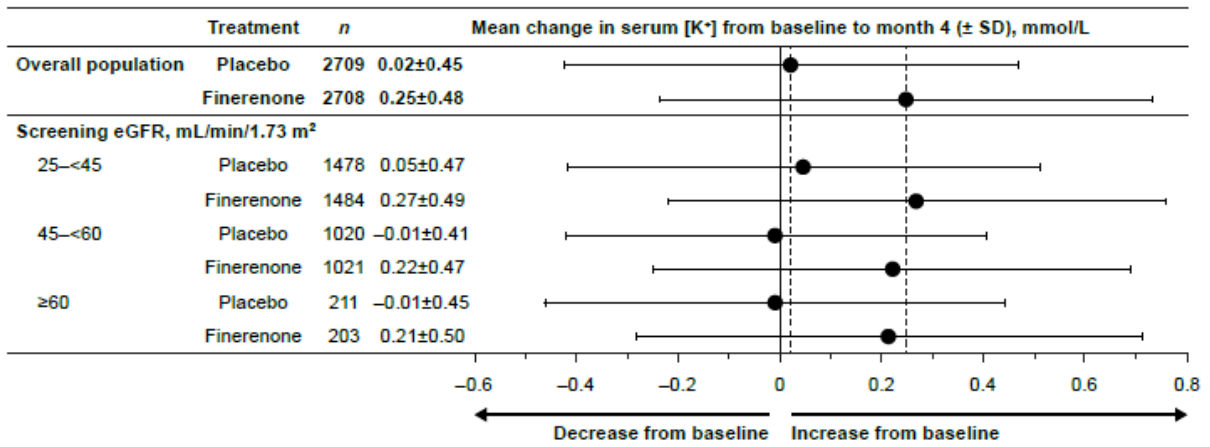


Figure S2. Mean change in serum potassium concentration from baseline to month 4 in the overall population and by eGFR category at the screening visit. eGFR, estimated glomerular filtration rate; SD, standard deviation.

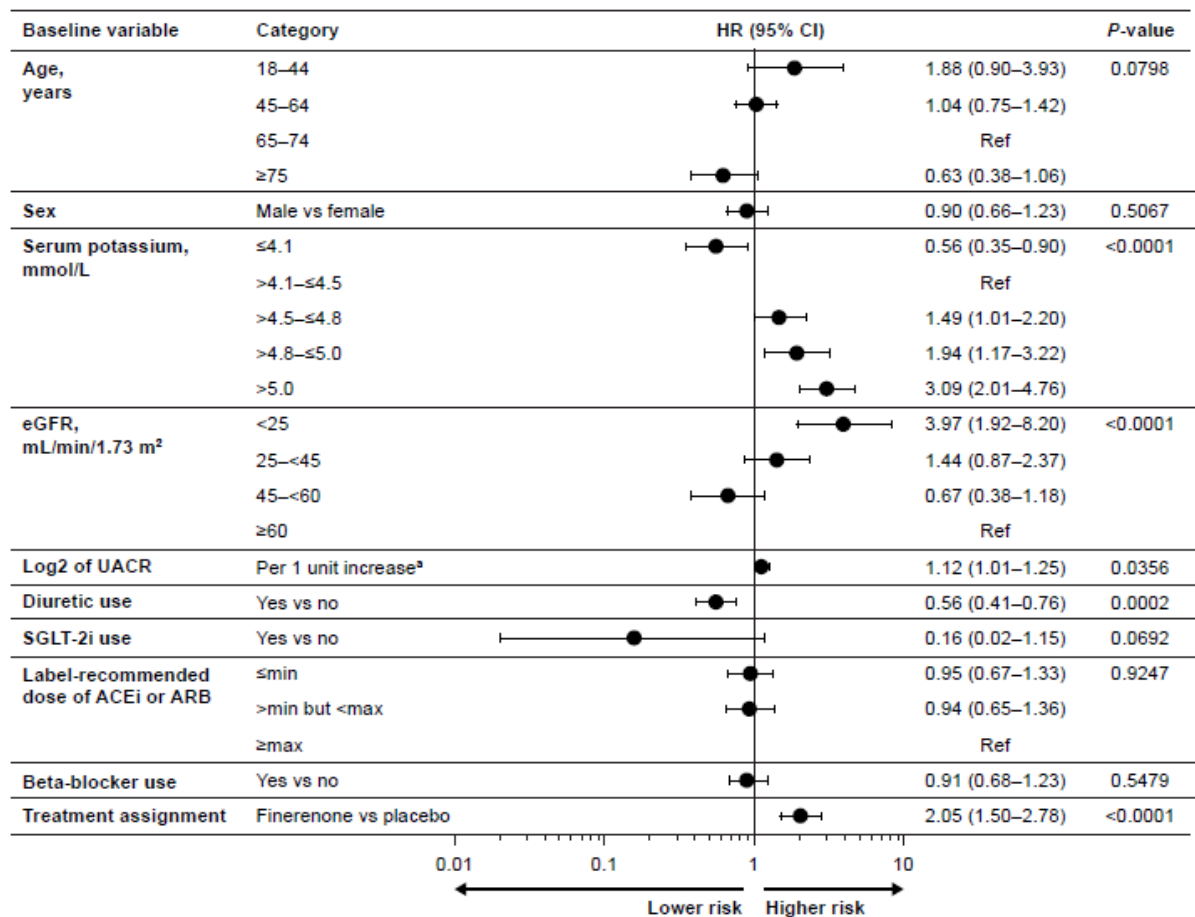


Figure S3. Multivariate analysis of time to any serum potassium concentration >6.0 mmol/L. ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CI, confidence interval; eGFR, estimated glomerular filtration rate; HR, hazard ratio; SGLT-2i, sodium-glucose co-transporter-2 inhibitor; UACR, urine albumin-to-creatinine ratio. ^aUACR is modelled as a continuous variable; 1 unit change in Log₂ UACR denotes doubling of UACR.

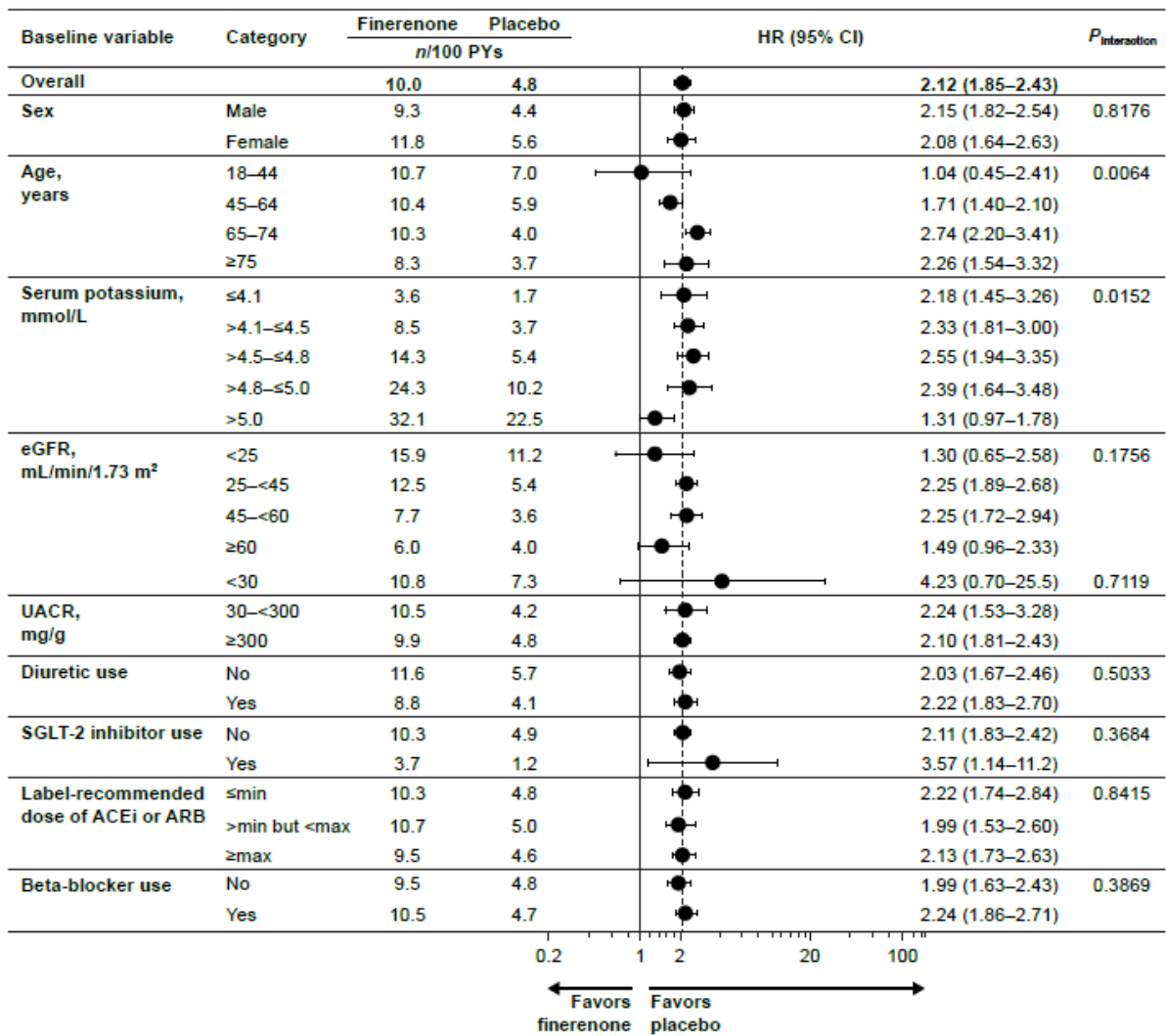


Figure S4. Impact of finerenone on hyperkalemia risk (serum potassium concentration >5.5 mmol/L) in patient subgroups. ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CI, confidence interval; eGFR, estimated glomerular filtration rate; HR, hazard ratio; PY, patient-year; SGLT-2, sodium-glucose co-transporter-2; UACR, urine albumin-to-creatinine ratio.

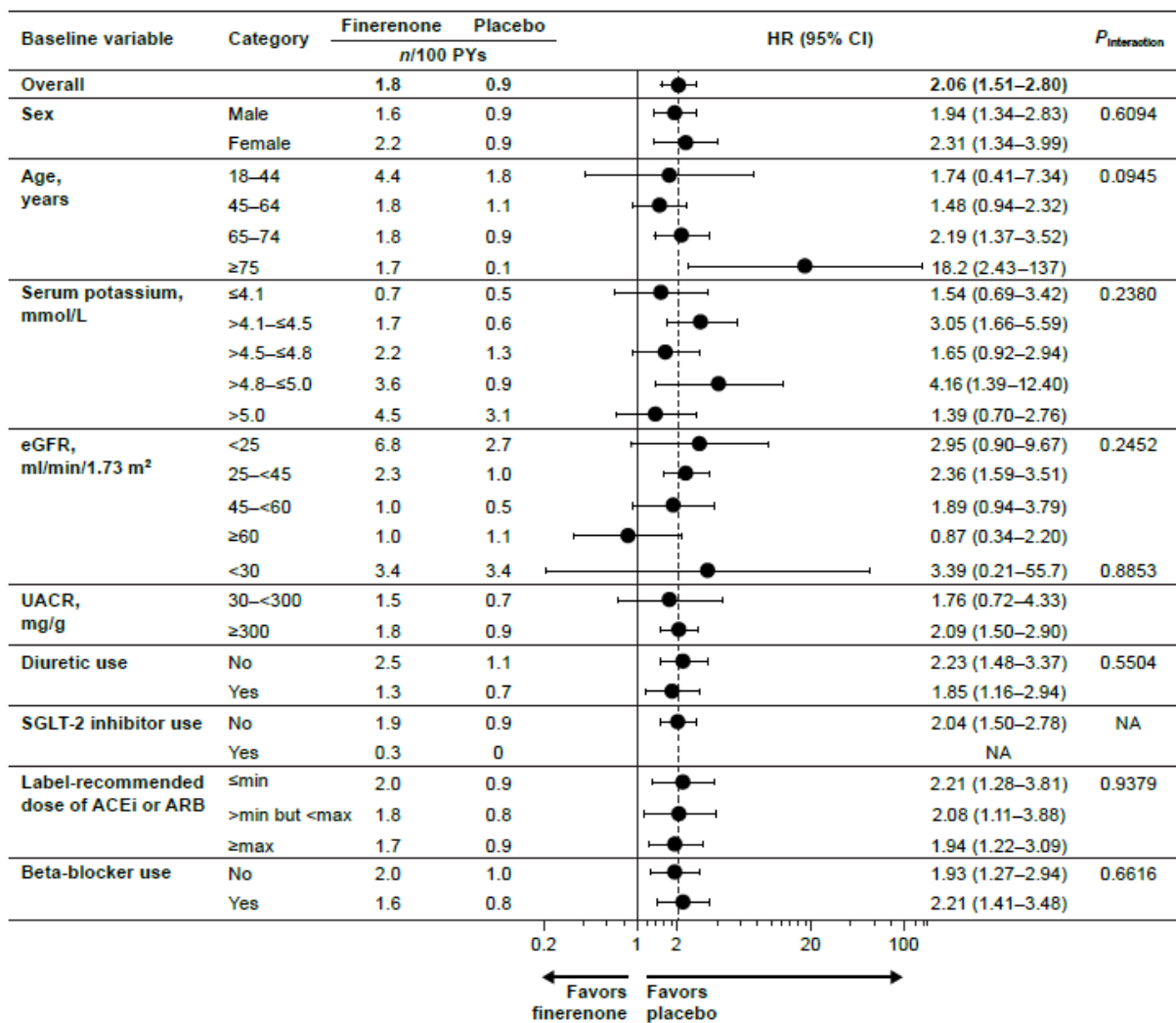


Figure S5. Impact of finerenone on hyperkalemia (serum potassium concentration >6.0 mmol/L) in patient subgroups. ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CI, confidence interval; eGFR, estimated glomerular filtration rate; HR, hazard ratio; PY, patient-year; SGLT-2, sodium-glucose co-transporter-2 inhibitor; UACR, urine albumin-to-creatinine ratio.

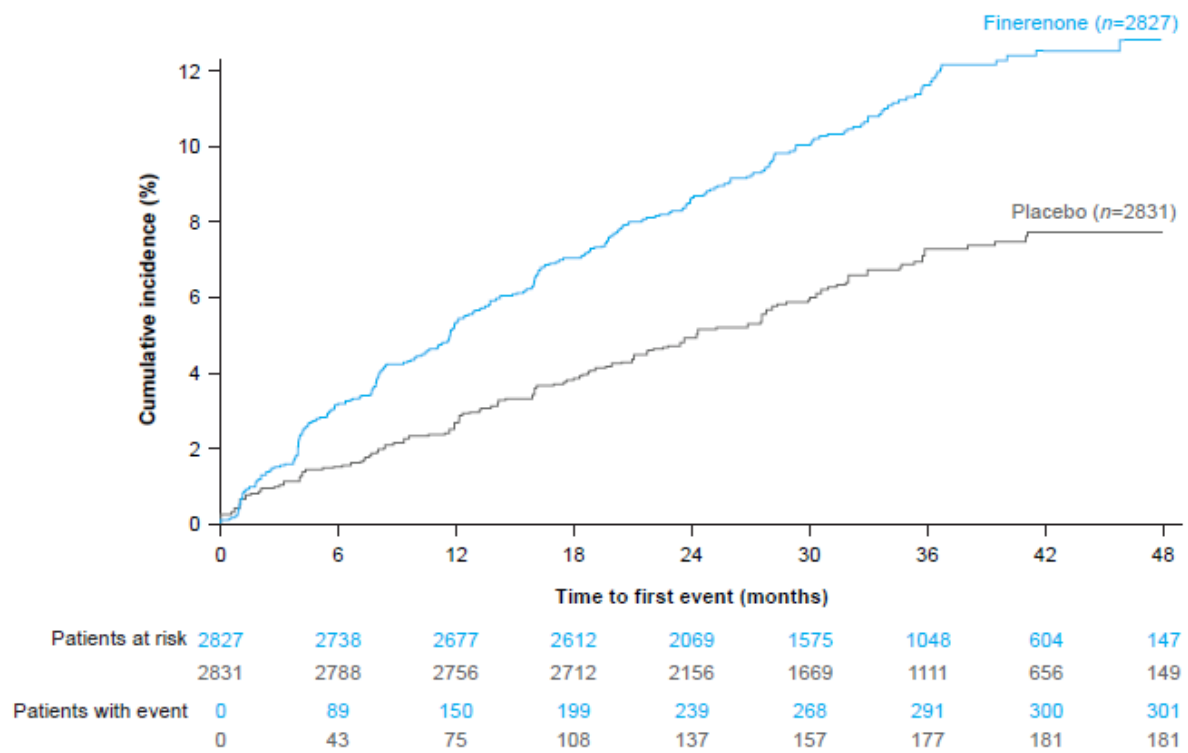


Figure S6. Time to first use of potassium binders.

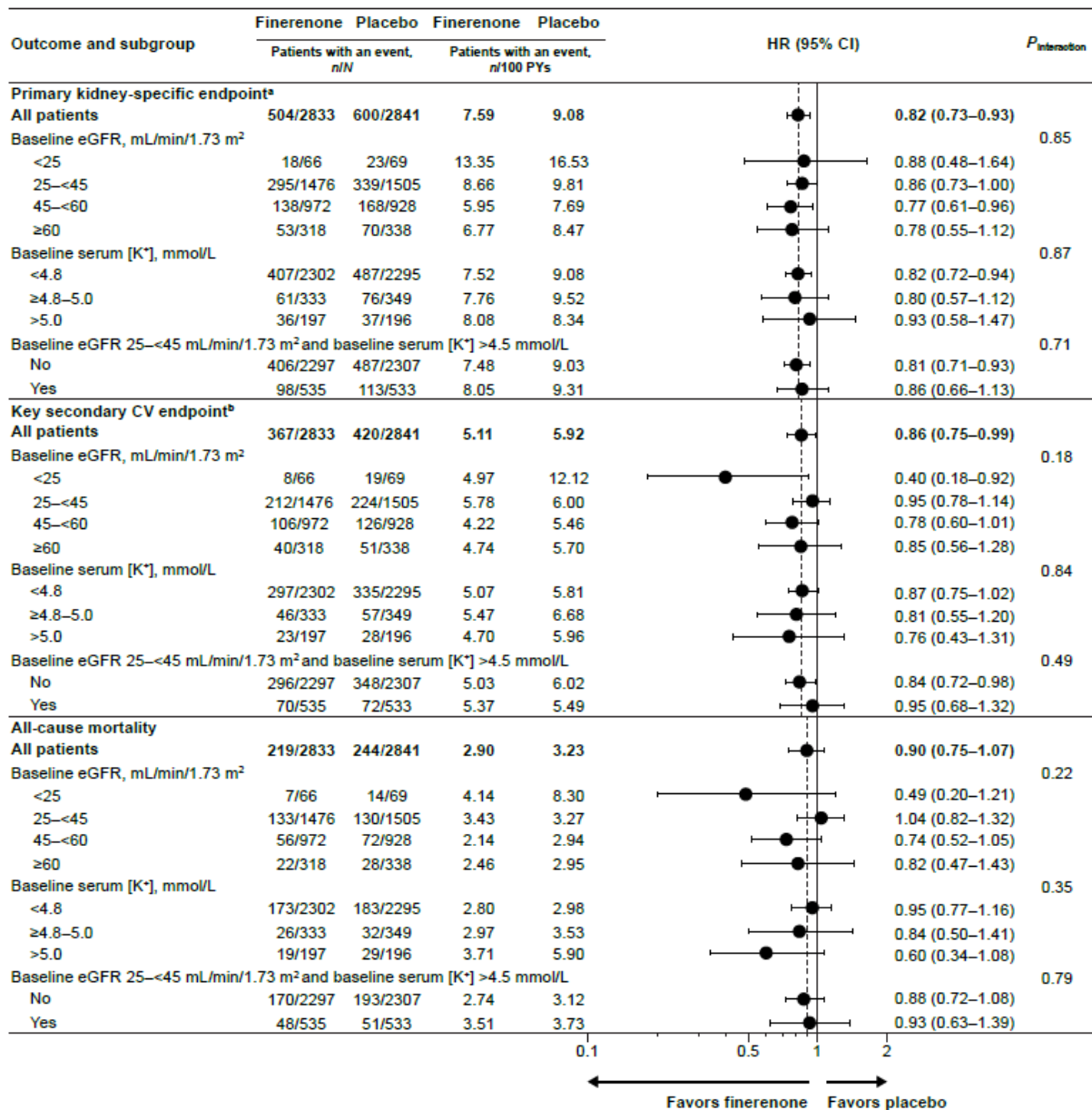


Figure S7. Primary composite kidney, key secondary composite CV, and all-cause mortality outcomes in patient subgroups at highest risk of hyperkalemia. CI, confidence interval; CV, cardiovascular; eGFR, estimated glomerular filtration rate; HR, hazard ratio; [K⁺], potassium concentration; MI, myocardial infarction; PY, patient-year. ^aTime to first onset of kidney failure, a sustained ≥40% decrease in eGFR from baseline over ≥4 weeks, or renal death; ^btime of first onset of CV death, non-fatal stroke, non-fatal myocardial infarction, or hospitalization for heart failure.

Supplemental Appendix 1. Full member list of the FIDELIO-DKD

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