

Supplementary Appendix

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Plain-Language Summary

Background

Frailty is a scale and relates to a person's ability to recover from health problems. As people get older and experience more health issues, their body becomes less able to cope with, and recover from, further injuries and illnesses. When this happens, a person is described as becoming more frail. People with higher levels of frailty are thought to have worse outcomes from disease but are also less likely to be given new medications, as many doctors think they may have too many side effects.

Why was this study needed?

Researchers wanted to see if finerenone, a medication that helps people with heart and kidney problems, could be safely and effectively used in people with varying levels of frailty.

How was this study done?

This study looked at the results of 12,990 people with chronic kidney disease and type 2 diabetes from across the world and how well finerenone worked at slowing down kidney damage, limiting heart disease, and if there were any side effects. These results were split into groups depending on how frail the people were at the beginning of the study.

What did this study find?

Finerenone helped people with kidney and heart problems regardless of how frail the participants who took part in the study were. People classed as more frail were more likely to experience side effects, but this was seen in those given finerenone or placebo (an inactive substance with no medical effect). This means finerenone may be useful for managing disease in people with chronic kidney disease and type 2 diabetes who are more frail.

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Statistical Analysis

For all efficacy analyses, events were considered from randomization to the end of study visit. When analyzing the composite outcomes and individual components, only the first event after randomization was considered. Events based on sustained decrease in eGFR were considered from randomization until 5 months after the last eGFR value was recorded at a clinic visit. Once an incident event occurred, a participant was no longer considered at risk. Treatment effects for time to event efficacy analyses within the subgroup levels were calculated using a stratified Cox proportional hazard model, which incorporated 120 different strata from the FIDELITY stratification factors: study (FIDELIO/FIGARO), region (North America/ Western Europe/ Eastern Europe/ Latin America/ Asia), type of albuminuria at screening (High/Very high), eGFR category at screening (3 categories), and CV disease history (Present/Absent).¹⁶ Within each stratum, the treatment effect was estimated at each level of the frailty subgroup, and these estimates were then combined to give a single hazard ratio for each frailty subgroup. The Cox proportional hazards models were adjusted for additional covariates of age, sex, race, body mass index, and systolic blood pressure. Interactions between treatment and subgroup were analyzed by including a treatment-by-subgroup interaction term in the model. Absolute risk differences between the event rates of finerenone and placebo were calculated using Mantel–Haenszel estimates and multiplying the value by 100, whereby a positive value equated to a risk reduction for finerenone compared with placebo. Interaction *P* values for absolute risk reduction included the subgroup and treatment interaction terms. When analyzing the secondary outcomes of all cause-mortality and all-cause hospitalization, cause-specific hazard ratios were used and, therefore, competing risks were controlled for through censoring criteria.

Analysis of changes in UACR included covariate factors of treatment group, the FIDELITY stratification factors, time, treatment*time, study, study*treatment, log-transformed baseline value nested within type of albuminuria at screening, and log-transformed baseline value*time. The treatment-by-visit interaction was included to model the rate of change in the treatment effect estimates over time. The study-by-treatment interaction was used to control for potential differences in treatment effects across the FIDELIO-DKD and FIGARO-DKD study populations used in this analysis. The baseline value-by-visit interaction was used to account for baseline values as well as model the relationship over time. An unstructured correlation matrix was specified to help account for the within participant correlations arising from the repeated measurements.

Supplement Table 1. Variables included in the frailty index

Variable	Category	Score
Lab values		
UACR, mg/g	30–300	0.5
	≥300	1
eGFR, mL/min/1.73 m ²	45–<60	0.5
	<45	1
Serum potassium, mmol/L	>4.8–≤5.0	0.5
	>5.0	1
Systolic blood pressure, mm Hg	≤90 or ≥140	1
Diastolic blood pressure, mm Hg	≥90	1
Pulse pressure	>55	1
HbA _{1c} , %	>7.5	1
Hemoglobin, g/dL	<13.2 (male)	1
	<11.6 (female)	
C-reactive protein, mg/dL	1.0–3.0	0.5
	>3.0	1
Demographics		
Diabetes duration, years	10–15	0.5
	>15	1
BMI, kg/m ²	25–29	0.5
	<18.5 or ≥30	1
Age, years	≥65	1
Gender	Male	1
EQ-5D questionnaire		
EQ-5D-5L (usual)	No problems	0
	Slight problems	0.25
	Moderate problems	0.5
	Severe problems	0.75
	Unable	1
EQ-5D-5L (mobility)	No problems	0
	Slight problems	0.25
	Moderate problems	0.5
	Severe problems	0.75
	Unable	1
EQ-5D-5L (pain)	None	0
	Slight	0.25

Variable	Category	Score
EQ-5D-5L (anxiety)	Moderate	0.5
	Severe	0.75
	Extreme	1
	None	0
	Slight	0.25
	Moderate	0.5
EQ-5D-5L (selfcare)	Severe	0.75
	Extreme	1
	No problems	0
	Slight problems	0.25
	Moderate problems	0.5
	Severe problems	0.75
EQ-5D-5L (selfcare)	Unable	1
Medical history		
History of HF	Yes	1
History of MI	Yes	1
History of stroke	Yes	1
History of CAD	Yes	1
History of retinopathy	Yes	1
History of hypertension	Yes	1
History of atrial fibrillation/ atrial flutter	Yes	1
History of hyperlipidemia	Yes	1
History of diabetic neuropathy	Yes	1
History of peripheral arterial occlusive disease	Yes	1
History of COPD	Yes	1
History of PCI or CABG	Yes	1

BMI, body mass index; CABG, coronary artery bypass surgery; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; EQ-5D, EuroQol-5 Dimension; HbA_{1c}, glycated hemoglobin; HF, heart failure; MI, myocardial infarction; PCI, percutaneous coronary intervention; UACR, urine albumin-to-creatinine ratio.