



FINERENONE: SUMMARY OF CARDIORENAL TRIALS

FIDELIO-DKD
2020

FIGARO-DKD
2021

DRUG	FIDELIO-DKD 2020		FIGARO-DKD 2021	
# RANDOMIZED	5734 (active, n=2833; placebo, n=2841)		7437 (active, n=3686; placebo, n=3666)	
INCLUSION CRITERIA	<ul style="list-style-type: none"> Type 2 diabetes Chronic kidney disease Receiving ACEi/ARB at maximally tolerated dose Serum potassium \leq4.8 mmol/L 		<ul style="list-style-type: none"> Type 2 diabetes Chronic kidney disease Receiving ACEi/ARB at maximally tolerated dose Serum potassium \leq4.8 mmol/L 	
BASELINE CHARACTERISTICS	<ul style="list-style-type: none"> Age ~66 years; male ~70% HgA1c ~7.7% eGFR ~44 mL/min; UACR ~852 mg/g 		<ul style="list-style-type: none"> Age ~64 years; male ~69% HgA1c ~7.7%; eGFR ~68 mL/min; UACR ~308 mg/g History of cardiovascular disease ~45% 	
DURATION	Median follow-up period of 2.6 years		Median follow-up period of ~3.4 years	
PRIMARY OUTCOME	Primary Renal Outcome: Composite of kidney failure, sustained decrease in eGFR \geq 40% or death from renal causes	Secondary CV Outcome: Composite of CV death, non-fatal MI, non-fatal stroke or HF hospitalization	Primary CV Outcome: Composite of CV death, non-fatal MI, non-fatal stroke or HF hospitalization	Secondary Renal Outcome: Composite of kidney failure, sustained decrease in eGFR \geq 40% or death from renal causes
RESULTS	Renal Composite Outcome: 504 (17.8%) vs 600 (21.1%) HR 0.82 (95% CI 0.73-0.93) p=0.001; ARR 3.33%; NNT ~30	CV Composite Outcome: 367 (13.0%) vs 420 (14.8%) HR 0.86 (95% 0.75-0.99) p=0.03; ARR 1.83%; NNT ~55	CV Composite Outcome: 458 (12.4%) vs 519 (14.2%) HR 0.87 (95% CI 0.76-0.98) p=0.03; ARR ~1.73%; NNT ~58	Renal Composite Outcome: NSD 350 (9.50%) vs 395 (10.8%) HR 0.87 (95% CI 0.76-1.01)
MORBIDITY OUTCOMES	Kidney Failure: NSD <u>Sustained Decrease in eGFR \geq 40%:</u> 479 (16.9%) vs 577 (20.3%) HR 0.81 (95% CI 0.72-0.92) ARR 3.40%; NNT ~30	Non-Fatal MI: NSD Non-Fatal Stroke: NSD HF Hospitalization: NSD	Non-Fatal MI: NSD Non-Fatal Stroke: NSD <u>Heart Failure Hospitalization</u> 117 (3.17%) vs 163 (4.44%) HR 0.71 (95% CI 0.56-0.90) ARR 1.27%; NNT ~79	Kidney Failure: NSD Sustained Decrease in eGFR \geq 40%: NSD
MORTALITY OUTCOMES	Renal Death: NSD	Cardiovascular Death: NSD	Cardiovascular Death: NSD	Renal Death: NSD
SAFETY	Hyperkalemia: 18.3% vs 9.01%		Hyperkalemia: 10.8% vs 5.28%	



These trials demonstrated the general **cardiovascular safety and benefit** of finerenone in patients with type 2 diabetes and chronic kidney disease. However, these trials show conflicting results in regards to renal outcomes (driven primarily by reduced rates of eGFR decline in the FIDELIO-DKD trial). The risk of hyperkalemia must be carefully considered against any potential treatment benefit.

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NSD: no significant difference