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Nephrologie

The CONFIDENCE trial



Presented at the 62nd European Renal Association Congress June 5, 2025



Presenters



Presented on behalf of the steering committee and CONFIDENCE investigators



Disclosures

 Peter Rossing Research support from AstraZeneca, Bayer, and Novo Nordisk, all made out to his institution Consulting fees from Abbott, Astellas, Bayer, Boehringer Ingelheim, Eli Lilly, Gilead, and Sanofi, all made out to his institution Payment or honoraria from Daiichi Sankyo, made out to his institution Support for attending meetings and/or travel from Bayer Receipt of trial drug for an investigator-initiated trial from Bayer, AstraZeneca, Novo Nordisk, and Lexicon Pharma 	 Hiddo J. L. Heerspink Consulting fees from Alexion, AstraZeneca, Bayer, Boehringer Ingelheim, BioCity, Dimerix, Eli Lilly, Janssen, Novartis, Novo Nordisk, Roche, and Travere Therapeutics, all paid to his employer Research support from AstraZeneca, Boehringer Ingelheim, Bayer, Janssen, and Novo Nordisk, all paid to his employer Honoraria from AstraZeneca and Novo Nordisk Travel expenses from AstraZeneca and Eli Lilly
 Rajiv Agarwal Nonfinancial support from Akebia Therapeutics, Alnylam, Bayer Healthcare Pharmaceuticals, Boehringer Ingelheim, Intercept, and Novartis Consulting fees from Akebia Therapeutics, Alnylam, Bayer Healthcare Pharmaceuticals, Boehringer Ingelheim, Intercept, and Novartis Royalties or licenses from UptoDate and Wolters Kluwer Member of the data safety monitoring committees for Chinook and Vertex Associate editor of the American Journal of Nephrology and Nephrology Dialysis Transplantation. Author and editor for UpToDate Research grants from the National Institutes of Health and the US Veterans Administration 	 Johannes F. E. Mann Grants from McMaster University (Hamilton, Canada), Novo Nordisk, and the European Union Consulting fees from Bayer and Novo Nordisk Honoraria from AstraZeneca, Bayer, Novartis, UpToDate, and Novo Nordisk Member of the data safety monitoring boards for Cytel, IQVIA, Parexel, WCG, and Sanofi Leadership role in the KDIGO group









Rationale of the trial

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Peter Rossing, MD, PhD



Foundations of treatment for patients with CKD and T2D



†ESC guidelines suggest fibrates along with lifestyle modifications in people who are statin intolerant with low HDL cholesterol and high triglyceride levels.

CKD, chronic kidney disease; ESC, European Society of Cardiology; HbA1c, glycated hemoglobin; HDL, high-density lipoprotein; PCSK9, proprotein convertase subtilisin/kexin type 9; T2D, type 2 diabetes. 1. Agarwal R et al. Nephrol Dial Transplant 2023;38:253–257; 2. Cosentino F et al. Eur Heart J 2020;41:255–323; 3. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. Kidney Int 2020;98:S1–S115; 4. American Diabetes Association Professional Practice Committee. Diabetes Care 2022;45(Suppl 1):S60–S82; 5. American Diabetes Association. Diabetes Care 2022;45(Suppl 1):S125–S143; 6. American Diabetes Association. Diabetes Care 2022;45(Suppl 1):S144–S174.



Rationale

Standard of care in T2D and CKD: four pillars



ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CKD, chronic kidney disease; GLP-1 RA, glucagon-like peptide-1 receptor agonist; ns-MRA, non-steroidal mineralocorticoid receptor antagonist; SGLT2i, sodium-glucose cotransporter 2 inhibitor; T2D, type 2 diabetes. 1. Agarwal R et al. Nephrol Dial Transplant 2023;38:253–257; 2. American Diabetic Association. Diabetes Care 2025;48:S239–S251.



Rationale

Simultaneous start of combination therapies in hypertension

Increased target BP achievement

Quicker and greater blood pressure reduction

Addresses multiple pathophysiologic pathways



Potential for better tolerability

Lower doses of two drugs may reduce dose-dependent side effects

Improved adherence

Single-pill combinations enhance adherence and consistent BP control

Rationale

Potential for improved CV outcomes



Guideline support

Major guidelines favor initial combination, especially for stage 2 hypertension or high CV risk



BP, blood pressure; CV, cardiovascular. Mancia G et al. Circ Res 2019;124:1113–1123.

Standard of care in HFrEF: four pillars



Implementation of the guidelines is evolving—some of all, instead of all of some^{1,2}

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; HFrEF, heart failure with reduced ejection fraction; MRA, mineralocorticoid receptor antagonist; SGLT2i, sodium-glucose cotransporter 2 inhibitor.



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1. Brownell NK et al. https://www.acc.org/Latest-in-Cardiology/Articles/2022/03/04/17/40/Simultaneous-vs-Sequential-Initiation-of-HFrEF-Therapies; 2. Hu J-R et al. Cardiol Clin 2023;41:511-524.

FIDELITY subgroup analysis: UACR reduction with Rationale finerenone is similar with and without an SGLT2i at baseline

• Reduced risk of kidney and CV outcomes with finerenone versus placebo

Outcome	HR	(95% CI)
CV composite		
SGLT2i at baseline	⊢	0.67 (0.42–1.07)
No SGLT2i at baseline	ю	0.87 (0.79–0.96)
Kidney composite		
SGLT2i at baseline	⊢	0.42 (0.16–1.08)
No SGLT2i at baseline	HI-HI-HI-HI-HI-HI-HI-HI-HI-HI-HI-HI-HI-H	0.80 (0.69–0.92)
HHF		
SGLT2i at baseline	⊢	0.44 (0.19–0.99)
No SGLT2i at baseline	⊢ ♦-	0.80 (0.68–0.95)
All cause death		
SGLT2i at baseline	F	0.58 (0.30–1.10)
No SGLT2i at baseline	н	0.90 (0.80–1.02)
	0.25 0.5	1 2
	Favors finerenone	Favors placebo

 Reduction in UACR (%) with finerenone versus placebo at Month 4



CV composite outcome comprised CV death, nonfatal myocardial infarction, nonfatal stroke, or HHF Kidney composite outcome comprised kidney failure, sustained ≥57% eGFR decline, or renal death

CV, cardiovascular; eGFR, estimated glomerular filtration rate; HHF, hospitalisation for heart failure; SGLT2i, sodium-glucose cotransporter 2 inhibitor; UACR, urine albumin-to-creatinine ratio... Rossing P et al. Diabetes Care 2022;45:2991–2998.



Additive effects of sMRA and SGLT2i on albuminuria

Methods

46 participants

- Diabetic and non-diabetic CKD
- Baseline urinary albumin excretion: 100–3500 mg/24 hours
- Baseline eGFR: >30-<90 mL/min/1.73 m²
- Stable (>4 weeks) dose of ACEi or ARB

Randomized

Cross-over trial: 4 weeks of treatment with 4-week washout

Treatments

Eplerenone 50 mg vs dapagliflozin 10 mg vs combination

Results		
	UACR reduction from baseline	
Eplerenone 50 mg	33.7%	
Dapagliflozin 10 mg	19.6%	
Combination therapy	53.0%	

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; sMRA, steroidal mineralocorticoid receptor antagonist; SGLT2i, sodium-glucose cotransporter 2 inhibitor; UACR, urinary albumin-creatinine ratio. Provenzano M et al. J Am Soc Nephrol 2022;33:1569–1580.



Additive effects of finerenone and SGLT2i on albuminuria

Methods		Results	
20 participants		UACR reduction from baseline	
 Non-diabetic CKD Baseline UACR: 150–2000 mg/g 	Finerenone	24% at week 4	
 Baseline eGFR: 25–45 mL/min/1.73 m² On maximal tolerated ACEi or ARB 	Dapagliflozin	8% at week 4	
Randomized to: 4 weeks with finerenone or dapagliflozin	Combination therapy	36% at week 8	
Followed by:			

4 weeks of combination therapy

This figure is adapted from Marup, et al. 2023 under the terms of the Creative Commons Attribution-Non-Commercial License (https://creativecommons.org/licenses/by-nc/4.0/). ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; SGLT2i, sodium-glucose cotransporter 2 inhibitor; UACR, urinary albumin-creatinine ratio. Marup FH et al. *Clin Kidney J* 2023;17:1569–1580.



CONFIDENCE hypothesis



A **combination** of **finerenone** and an **SGLT2i** would decrease albuminuria more than either treatment alone

The trial also aimed to establish the safety of the combination



Blood pressure

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eGFR



eGFR, estimated glomerular filtration rate; SGLT2i, sodium-glucose cotransporter 2 inhibitor.

Hypothesis







Trial design and baseline characteristics

Hiddo J. L. Heerspink, PhD



CONFIDENCE trial design



[†]Participants with an eGFR of 40–90 mL/min/1.73 m² were recruited (Part A) prior to recruiting participants with an eGFR of 30–90 mL/min/1.73 m² (Part B). ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; HbA1c, glycated hemoglobin; HFrEF, heart failure with reduced ejection fraction; K⁺, potassium; NYHA, New York Heart Association; R, randomization; SGLT2i, sodium-glucose cotransporter 2 inhibitor; T1D, type 1 diabetes; T2D, type 2 diabetes; UACR, urinary albumin-to-creatinine ratio. **CONFIDENCE: NCT05254002; EudraCT 2021-003037-11.**



CONFIDENCE trial design

Participants were randomized in a 1:1:1 ratio to one of three parallel groups



This figure is adapted from Green JB, et al. under the terms of the Creative Commons Attribution-Non-Commercial License (https://creativecommons.org/licenses/by-nc/4.0/). [†]Participants with an eGFR of 40–90 mL/min/1.73 m² were recruited (Part A) prior to recruiting participants with an eGFR of 30–90 mL/min/1.73 m² (Part B). The number of participants will be capped in parts A and B as follows: 80% with an eGFR of ≤75 mL/min/1.73 m² and 20% with an eGFR of >75 mL/min/1.73 m². Up/down titration based on eGFR, serum/plasma potassium, or safety and tolerability. ABPM, ambulatory blood pressure monitoring; eGFR, estimated glomerular filtration rate; R, randomization; UACR, urinary albumin-to-creatinine ratio. Green JB et al. Nephrol Dial Transplant 2023;38:894–903. **CONFIDENCE: NCT05254002; EudraCT 2021-003037-11**.



CONFIDENCE trial design





CKD, chronic kidney disease; SD, standard deviation; UACR, urinary albumin-to-creatinine ratio.

1. Green JB et al. Nephrol Dial Transplant 2023;38:894–903; 2. Heerspink HJL et al. Lancet Diabetes Endocrinol 2019;7:128–139. CONFIDENCE: NCT05254002; EudraCT 2021-003037-11.





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CONFIDENCE: trial population



Trial sites



818 participants were randomized across 143 sites in 14 countries/regions

- Belgium
- Canada
- Denmark
- France
- Germany
- India
- Israel
- Italy
- Japan
- The Netherlands
- Republic of Korea
- Spain
- Taiwan
- United States of America



Patient disposition



[†]Top screening failure reasons: not meeting inclusion criteria (CKD diagnosis) or meeting exclusion criteria (serum potassium ≥4.8 mmol/L). [‡]Percentage of screened participants who were randomized. SExclusion required by Japanese authority.

CKD, chronic kidney disease; FAS, full analysis set; GCP, Good Clinical Practice.

Baseline demographics

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Data shown are means and proportion of participants.

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ASCVD, atherosclerotic cardiovascular disease; BMI, body mass index; eGFR, estimated glomerular filtration rate; GLP-1RA, glucagon-like peptide-1 receptor agonist; HbA1c, glycated hemoglobin; K⁺, potassium; SBP, systolic blood pressure; UACR, urinary albumin-to-creatinine ratio.









Efficacy and safety

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Rajiv Agarwal, MD, MS







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CONFIDENCE: **UACR** endpoints



Questions for the audience



At 6 months, **what percentage reduction in UACR** would you expect to see in the combination group?

A. < 20 % B. 20 - 30 % C. 30 - 40 % D. 40 - 50 % E. 50 - 60 % F. > 60 %







Primary endpoint



[†]Percentage change calculation = (least squares mean ratio to baseline – 1) × 100. BL, baseline; Cl, confidence interval; SGLT2i, sodium-glucose cotransporter 2 inhibitor; UACR, urinary albumin-to-creatinine ratio.



Primary endpoint







Primary endpoint







[†]Percentage change calculation = (least squares mean ratio to baseline – 1) × 100. BL, baseline; CI, confidence interval; SGLT2i, sodium-glucose cotransporter 2 inhibitor; UACR, urinary albumin-to-creatinine ratio.



70% of patients achieved >30% reduction in UACR with simultaneous initiation of finerenone and SGLT2i



[†]The denominator represents all participants at risk for a treatment-emergent laboratory abnormality. Participants must have both a BL and post BL value and the BL value must be in the expected range for that criteria. BL, baseline; SGLT2i, sodium-glucose cotransporter 2 inhibitor; UACR, urinary albumin-to-creatinine ratio. 1. American Diabetes Association Professional Practice Committee. Diabetes Care 2025;48(Suppl 1):S239–S251.



64% of patients achieved >40% reduction in UACR with simultaneous initiation of finerenone and SGLT2i

UACR endpoints

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[†]The denominator represents all participants at risk for a treatment-emergent laboratory abnormality. Participants must have both a BL and post BL value and the BL value must be in the expected range for that criteria. BL, baseline; SGLT2i, sodium-glucose cotransporter 2 inhibitor; UACR, urinary albumin-to-creatinine ratio.



55% of patients achieved >50% reduction in UACR with simultaneous initiation of finerenone and SGLT2i

UACR endpoints

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[†]The denominator represents all participants at risk for a treatment-emergent laboratory abnormality. Participants must have both a BL and post BL value and the BL value must be in the expected range for that criteria. BL, baseline; SGLT2i, sodium-glucose cotransporter 2 inhibitor; UACR, urinary albumin-to-creatinine ratio.



[K+] increased in combination and finerenone groups, returning to BL levels after drug withdrawal





Safety

[K+] increased in combination and finerenone groups, returning to BL levels after drug withdrawal





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[K+] increased in combination and finerenone groups, returning to BL levels after drug withdrawal





Numerically lower incidence of treatment-emergent hyperkalemia with combination therapy compared with finerenone

Safety







Numerically lower incidence of treatment-emergent hyperkalemia with combination therapy compared with finerenone

Safety





Treatment-emergent hyperkalemia events leading to permanent discontinuation of trial drug were uncommon

	Combination N = 268 ⁺	Finerenone N = 264 [†]	Empagliflozin N = 266 ⁺	
Treatment-emergent hyperkalemia,‡ n				
Leading to hospitalization	0	0	0	
Leading to permanent discontinuation of trial drug	1	1	1	
Serious adverse event	0	0	0	
Leading to death	0	0	0	

[†]SAS comprised all participants receiving at least one dose of trial medication. [‡]Adverse events were defined as TEAEs if they occurred in patients who had received at least one dose of trial treatment and that started or worsened after the first dose of trial treatment and up to 3 days after any temporary or permanent interruption of trial treatment. The denominator represents all participants at risk for a treatment-emergent laboratory abnormality. Participants must have had both a BL and post-BL treatment-emergent value while the BL value must not have exceeded the displayed threshold. The numerator represents the number of participants at risk with at least one treatment-emergent laboratory assessment meeting the criterion. BL, baseline; SAS, safety analysis set; TEAE, treatment-emergent adverse event.



Combination therapy had an additive impact on SBP





Combination therapy had an additive impact on SBP





Combination therapy had an additive impact on SBP





Incidence of symptomatic hypotension was low

Symptomatic hypotension incidence





Safety

Initial eGFR decline following simultaneous initiation of combination therapy was predictable

Findings suggest eGFR changes are hemodynamic



Least-squares mean difference (95% CI) for the mixed model repeated measures analysis of change from baseline in eGFR. eGFR was calculated by the Chronic Kidney Disease Epidemiology Collaboration equation with a modification to the equation for Japanese participants.

BL, baseline; CI, confidence interval; eGFR, estimated glomerular filtration rate.



Initial eGFR decline following simultaneous initiation of combination therapy was predictable

Findings suggest eGFR changes are hemodynamic



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Safety

Initial eGFR decline following simultaneous initiation of combination therapy was predictable

Findings suggest eGFR changes are hemodynamic



Least-squares mean difference (95% CI) for the mixed model repeated measures analysis of change from baseline in eGFR. eGFR was calculated by the Chronic Kidney Disease Epidemiology Collaboration equation with a modification to the equation for Japanese participants.



Safety

BL, baseline; CI, confidence interval; eGFR, estimated glomerular filtration rate.

Initial eGFR decline following simultaneous initiation of combination therapy was predictable and largely reversible after drug withdrawal



Least-squares mean difference (95% CI) for the mixed model repeated measures analysis of change from baseline in eGFR. eGFR was calculated by the Chronic Kidney Disease Epidemiology Collaboration equation with a modification to the equation for Japanese participants.

BL, baseline; CI, confidence interval; eGFR, estimated glomerular filtration rate.



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Low incidence of AKI after simultaneous initiation of Safety Combination therapy



Incidence of adverse events leading to drug discontinuation was low



Summary

Simultaneous initiation of finerenone and an SGLT2i provides early and additive effects on UACR reduction that are statistically and clinically significant

Symptomatic hypotension, acute kidney injury, and hyperkalemia leading to drug discontinuation were uncommon









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Interpretation

Johannes F. E. Mann, MD



Does albuminuria reduction mediate CKD outcomes in T2D?





Interpretation

Causal mediation analysis of UACR on kidney and CV outcomes







Interpretation

Percent of outcomes mediated by an early (baseline to 4 months) UACR reduction



Early albuminuria reduction with finerenone in CKD and T2D mediates a large proportion of the treatment effect against CKD progression and a modest proportion of the effect against CV outcomes



Early treatment effect on albuminuria associates with long-term kidney outcomes



Association **≠** Causation

Median time to albuminuria = 6 months



Heerspink HJL et al. Lancet Diab Endo 2019, DOI 10.1016/S2213-8587(18)30314-0

Interpretation

Percent of CV outcomes mediated by an early (baseline to 4 months) UACR reduction and BP is additive



Early albuminuria and BP reductions with finerenone in CKD and T2D jointly mediated half of the CV outcome

⁺Fewer participants were analyzed in this data set due to Good Clinical Practice violations at one site; therefore, the UACR mediation is not identical to the prior analysis. BP, blood pressure; CV, cardiovascular; SBP, systolic blood pressure; T2D, type 2 diabetes; UACR, urinary albumin-to-creatinine ratio. Agarwal R et al. J Am Coll Cardiol 2025; 85(SupplA):424.



Interpretation

CKD progression can potentially be slowed by combination therapy





Summary

Evidence demonstrates the combined benefits of multiple pillars of therapy and that potentially greater benefits can be achieved through early and intensive intervention Findings show that finerenone and an SGLT2i can be initiated simultaneously





Thank you to our investigators, staff, and trial participants

Steering committee: Rajiv Agarwal, MD, MS, MBBS, FASN (Chair), Roudebush VA Medical Centre and Indiana University School of Medicine; Janet B. McGill, MD, Washington University in St. Louis; Amy K. Mottl, MD, UNC School of Medicine; Johannes F. E. Mann, MD, KfH Kidney Centre Munich and Friedrich Alexander University; Peter Rossing, MD, Steno Diabetes Center Copenhagen and University of Copenhagen; Masaomi Nangaku, MD, PhD, The University of Tokyo Graduate School of Medicine; Jennifer B. Green, MD, Duke University School of Medicine; George L. Bakris (former member of the steering committee), MD, University of Chicago Medicine; Hiddo J. L. Heerspink, PhD, University Medical Centre Groningen; Julio Rosenstock, MD, Velocity Clinical Research at Medical City; Muthiah Vaduganathan, MD, MPH, Brigham and Women's Hospital and Harvard Medical School.

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Thank you to the data monitoring committee and national/regional lead investigators

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ORIGINAL ARTICLE

Finerenone with Empagliflozin in Chronic Kidney Disease and Type 2 Diabetes

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